ISRCTN55471843 https://doi.org/10.1186/ISRCTN55471843

Clinical trial for the treatment of COVID-19 and COVID-like illness in primary care

Submission date
03/11/2022

Recruitment status
No longer recruiting

Registration date
21/11/2022

Overall study status
Completed

Last Edited
16/06/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Most people with COVID-19 and COVID-like illness do not become seriously ill. Some people, however, do go on to have more serious symptoms and may even need to be admitted to hospital. The aim of this study is to investigate the effectiveness and safety of investigational products to treat COVID-19 and COVID-like illness in adult patients across Europe. This study will investigate whether the medicinal products help patients to recover faster, reduce the severity of the symptoms, reduce complications that require treatment in hospital, and clear the viral pathogen faster.

Who can participate?
Patients aged 18 years or over and experiencing symptoms of a COVID-19 or COVID-like illness, presenting to primary care or recruited from the community in Belgium, France, Germany, Ireland, Poland, Spain, the UK and Georgia

What does the study involve?
Participants will be randomly allocated to receive either usual care alone or an investigational product, a placebo or a comparator product in addition to usual care.
Participants allocated to the Usual Care group will receive usual clinical care. Participants allocated to Usual Care + Nitric Oxide Nasal Spray will additionally receive Nitric Oxide Nasal Spray (NONS) administered intranasally (into the nose), six times per day (two sprays per nostril, equivalent to a 0.50 ml volume total per dose [four sprays]), for 7 days.
Participants allocated to usual care + saline nasal spray will receive a 0.9% NaCl solution administered intranasally in addition to usual care, six times per day (two sprays per nostril, equivalent to 0.50 ml volume total per dose [four sprays]), for 7 days. Participants allocated to the usual care + LTX-109 will receive LTX-109 0.5% weight/weight administered intranasally, three times per day (one spray per nostril, equivalent to 280 µL volume total per dose [two sprays]) for 3 days.
Participants allocated to the usual care + LTX-109-placebo will receive LTX-109 0.0% weight /weight administered intranasally, three times per day (one spray per nostril, equivalent to 280 µL volume total per dose [two sprays]) for 3 days.
The duration of the study for each participant is intervention-specific, appendix- and phase-dependent. Participants will be monitored daily for their acute symptoms for 28 days with a

diary. They will receive a phone call between 28 days and 35 days in case data capture is not complete. Longer-term follow-up will be at 3 months by a phone call or electronic questionnaire. A combined throat/nose swab will be taken at the start of the study and on day 4 for NONS and saline and at the start of the study and on days 1, 3 and 5 for LTX-109 and LTX-109-placebo.

What are the possible benefits and risks of participating?
The overall benefits for participants in the intervention group are related to the potential treatment effects of the investigational product on their COVID-19 or COVID-like illness duration and/or severity. Taking part in the study can have possible disadvantages. Participants may experience side effects from the investigational product. There may be a brief period of discomfort from (self-)taking the combined throat/nose swabs. Taking part in the study will take up some of the time of the participant.

Where is the study run from?
This study is being led by the University Medical Center Utrecht (UMCU) and managed by Ecraid (European Clinical Research Alliance on Infectious Diseases) in the Netherlands. It is a collaboration between the UMCU, the University of Oxford (UK), the University of Antwerp (Belgium), ECRIN (European Clinical Research Infrastructure Network, France) and Ecraid.

When is the study starting and how long is it expected to run for?
December 2021 to July 2026

Who is funding the study?
European Union

Who is the main contact?
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Clinical Trials Information System (CTIS)
2022-501707-27-01

Integrated Research Application System (IRAS)
1008573

Protocol serial number
EU-EcraidPC-1

Study information

Scientific Title
European Clinical Research Alliance on Infectious Diseases – primary care adaptive platform trial for pandemics and epidemics

Acronym
ECRAID-Prime

Study objectives
The study record was updated on 13/01/2026 with the current study objectives associated with protocol version 7 dated 10/07/2025:
To assess the efficacy of the study investigational product (IP) versus control (usual care) or versus a comparator (placebo or comparator IP) on:
1. Time to first self-report of feeling recovered from symptoms of COVID-19 or COVID-like illness (for Phase IIb/III type evaluation, as specified in the relevant intervention-specific appendix).
2. Viral clearance and potentially viral load and/or impact on biomarkers, for example, on illness severity or immunological response (for Phase IIa type evaluation as specified in the relevant intervention-specific appendix).

The study record was updated on 23/07/2024 with the study objectives associated with protocol version 5 dated 22/03/2024:
The primary objective(s) of this platform study will be phase-dependent.
To assess the efficacy of the study IP versus control on:
1. Time to first self-report of feeling recovered from symptoms of COVID-19 or COVID-like illness (for Phase IIb/III type evaluation, as specified in the relevant intervention-specific appendix).
2. Viral clearance and potential impact on biomarkers, for example, on illness severity or immunological response (for Phase IIa type evaluation as specified in the relevant intervention-specific appendix).

Initial study hypothesis:
To test the safety and efficacy of treatments for patients presenting to primary care with COVID-19 and COVID-like illness in a Phase II/III type evaluation, with the aim of determining whether treatments should progress to the next phase of evaluation, and evaluate the trial process and procedures in order to optimise them and enhance recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/06/2024, Clinical Trial Regulation (CTR) in the Clinical Trials Information System (Domenico Scarlattilaan 6, Amsterdam, 1083 HS, Netherlands; +31 (0)88 781 6000; certificate@ema.europa.eu), ref: 2022-501707-27-01
2. Approved 12/04/2024, Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC) (10 South Colonnade United Kingdom, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: IRAS ID 1008573
3. Approved 28/01/2025, Georgian Ministry of Health (Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs 144, Ak. Tsereteli Ave., Tbilisi, 0119, Georgia; +995 (0)32 2 51 00 26; info@moh.gov.ge), ref: No: 00085

Primary study design
Interventional

Study design
Adaptive platform randomized comparative multicentre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory tract infections, COVID-19, and COVID-like illness

Interventions
The study record was updated on 08/06/2026 with the current study interventions associated with protocol version 7 dated 10/07/2025 to improve readability:
The ECRAID-Prime trial is a platform trial which means that multiple investigational products for the same illness can be tested simultaneously, and new interventions can be added during the course of the trial in accordance with pre-specified criteria. The names of all treatments of actions, including the control and details of the interventions (dose, duration, and how they are administered), are intervention-specific and will be described in intervention-specific appendices that will be added to the master protocol.

Participants will be randomized to receive either usual care alone or an investigational product, a placebo or a comparator product in addition to usual care. Potential participants can be included if they are eligible to be randomized to at least one investigational product, as well as the usual care arm.

Up to this point the following interventions have been included in the trial:
A. Usual Care

Participants randomized to Usual Care will receive usual clinical primary care according to standard care in the specific country, at the discretion of responsible treating clinicians. Additional inclusion and exclusion criteria may apply based on comparator arms.

B. Usual Care + Nitric Oxide Nasal Spray
Nitric Oxide Nasal Spray (NONS) is a nitric oxide donor that is expected to have a broad-acting antiviral effect and to accelerate viral clearance in patients infected with SARS-CoV-2 and other respiratory viruses. NONS will be administered intranasally, six times per day [two sprays per nostril, equivalent to 0.50 mL volume total per dose (4 sprays)] for 7 days.

C. Usual Care + Saline Nasal Spray
Saline is a 0.9% NaCl solution with possible antiviral and/or virus-washing-out activity. Saline will be administered intranasally six times per day (two sprays per nostril, equivalent to a 0.50 ml volume total per dose [two sprays]) for 7 days.

Note: ECRAID-Prime started with arms A, B and C, where usual care is the control for saline nasal spray, and saline nasal spray is the comparator for NONS.

D. Usual Care + LTX-109
LTX-109 is a broad-acting antiviral and antibacterial agent which disrupts the viral envelope and lyses the bacterial membrane, thereby inactivating viruses and bacteria. It is expected to accelerate viral/pathogen clearance in patients with respiratory infections. LTX-109 (0.5% weight /weight [w/w]) will be administered intranasally, three times per day (one spray per nostril, equivalent to 280 µL volume per dose [two sprays]), for 3 days.

Note: The comparator for LTX-109 0.5% is LTX-109 placebo 0.0%.

The study record was updated on 13/01/2026 with the study interventions associated with protocol version 7 dated 10/07/2025:
Eligible participants will be randomly allocated to receive either an investigational product (IP) or the specified control. Each investigational product has a matching placebo or comparator. Besides this matching placebo or comparator IP, usual care alone can be an additional control arm, this comparison is not double-blind. Participants will be randomised to receive either usual care alone or an investigational product, a placebo or a comparator product in addition to usual care.

The ECRAID-Prime trial is a platform trial which means that multiple investigational products for the same illness can be tested simultaneously, and new interventions can be added during the course of the trial in accordance with pre-specified criteria. The names of all treatments of actions, including the control and details of the interventions (dose, duration, how it is administered) are intervention specific and will be described in intervention-specific appendices that will be added to the master protocol. Up to this point three investigational products have been selected.

Participants will be randomized to receive either usual care alone or an investigational product, a placebo or a comparator product in addition to usual care. Potential participants can be included if they are eligible to be randomized to at least one investigational product, as well as the usual care arm.

A. Usual care arm
Participants randomized to the usual care arm will receive usual clinical care according to standard care in the specific country, at the discretion of responsible treating clinicians and

according to the participant's own decisions about self-care for the specific respiratory tract infection.

B. Usual care + nitric oxide nasal spray
Nitric oxide nasal spray (NONS) is a nitric oxide donor. NONS will be administered intranasally in addition to usual care, six times per day [two sprays per nostril, equivalent to 0.45 ml volume total per dose (four sprays)], for 7 days.

C. Usual care + saline nasal spray
Saline is a saltwater solution and will be administered intranasally in addition to usual care, six times per day [two sprays per nostril, equivalent to 0.45 ml volume total per dose (four sprays)], for 7 days.

D. Usual care + LTX-109
LTX-109 is a broad-acting antiviral and antibacterial agent and will be administered intranasally in addition to usual care, three times per day [1 spray per nostril, equivalent to 280 uL volume per dose (2 sprays)], for 3 days.

Initial interventions associated with protocol version 5 dated 22/03/2024:
Eligible participants will be randomly allocated to receive either an investigational product (IP) or the specified control. Each investigational product has a matching placebo or comparator. Besides this matching placebo or comparator IP, usual care alone can be an additional control arm, this comparison is not double-blind. Participants will be randomised to receive either usual care alone or an investigational product, a placebo or a comparator product in addition to usual care.

The ECRAID-Prime trial is a platform trial which means that multiple investigational products for the same illness can be tested simultaneously, and new interventions can be added during the course of the trial in accordance with pre-specified criteria. The names of all treatments of actions, including the control and details of the interventions (dose, duration, how it is administered) are intervention specific and will be described in intervention-specific appendices that will be added to the master protocol. Up to this point two investigational products have been selected.

Participants will be randomized to receive either usual care alone or an investigational product, a placebo or a comparator product in addition to usual care. Potential participants can be included if they are eligible to be randomized to at least one investigational product, as well as the usual care arm.

A. Usual care arm
Participants randomized to the usual care arm will receive usual clinical care according to standard care in the specific country, at the discretion of responsible treating clinicians and according to the participant's own decisions about self-care for the specific respiratory tract infection.

B. Usual care + nitric oxide nasal spray
Nitric oxide nasal spray (NONS) is a nitric oxide donor. NONS will be administered intranasally in addition to usual care, six times per day [two sprays per nostril, equivalent to 0.45 ml volume total per dose (four sprays)], for 7 days.

C. Usual care + saline nasal spray
Saline is a saltwater solution and will be administered intranasally in addition to usual care, six

times per day [two sprays per nostril, equivalent to 0.45 ml volume total per dose (four sprays)], for 7 days.

Intervention Type
Other

Primary outcome(s)
The study record was updated on 08/06/2026 with the current primary outcome measures associated with protocol version 7 dated 10/07/2025 to improve readability:
For Phase IIb/III-type evaluations, the primary outcome will be:
Time to first self-report of feeling fully recovered from symptoms related to COVID-19 or COVID-like illness, measured in days using a daily diary for 28 days and, if not recovered within 28 days, a questionnaire at month 3.

For Phase IIa-type evaluations the primary outcome parameter can be either (specified in the intervention-specific appendix):
1. Viral clearance measured from a combined nose/throat swab sample using semi-quantitative PCR on an intervention-specific appendix specified day (Day 3 for the LTX-109 evaluation) OR
2. Impact on biomarkers of illness severity, or immunological response from a blood sample using an appropriate analysis method on an intervention-specific appendix specified day

The study record was updated on 13/01/2026 with the primary outcome measures associated with protocol version 7 dated 10/07/2025:
The primary outcome will be phase-dependent. For Phase IIb/III-type evaluations, the primary outcome will be:
1. Time to first self-report of feeling fully recovered from symptoms related to COVID-19 or COVID-like illness (days), measured using self-report for 28 days (or month 3 if not recovered).

For Phase IIa-type evaluations the primary outcome parameter will be:
2. Viral clearance measured using semi-quantitative PCR at baseline and on day 4, and impact on biomarkers of illness severity (if this will be an outcome parameter, then this will be specified in the intervention-specific appendix). The impact on biomarkers, for example, on illness severity or immunological response is dependent on the specific investigational product (also the method and timepoints are dependent on the investigational product). If this will be an outcome parameter, then this will be specified in the intervention-specific appendix of that investigational product.

The study record was updated on 23/07/2024 with the primary outcome measures associated with protocol version 5 dated 22/03/2024:
The primary outcome will be Phase dependent. For Phase IIb/III type evaluations the primary outcome will be:
1. Time to first self-report of feeling fully recovered from symptoms related to COVID-19 or COVID-like illness (days), measured using self-report for 28 days (or months 3 and 6 if not recovered).

For Phase IIa type evaluations the primary outcome parameter will be:
2. Viral clearance assessed using semi-quantitative PCR at baseline and on days 4, 7 and 14, and impact on biomarkers of illness severity (if this will be an outcome parameter, then this will be specified in the intervention-specific appendix). The impact on biomarkers, for example, on illness severity or immunological response is dependent on the specific investigational product (also the method and timepoints are dependent on the investigational product). If this will be an outcome parameter, then this will be specified in the intervention-specific appendix of that

investigational product. So far, there are no compounds selected for which this will be an outcome parameter.

The study record was updated on 03/02/2023 with the primary outcome measures associated with a prior non-approved protocol version:
Primary study endpoints are dependent on the study phase and can be:
1. Time to first self-report of feeling fully recovered from symptoms related to COVID-19 or COVID-like illness (days), measured using self-report for 28 days (or months 3 and 6 if not recovered).
2. Viral clearance assessed using semi-quantitative PCR at baseline and on days 4, 7 and 14, and impact on biomarkers of illness severity (if this will be an outcome parameter, then this will be specified in the intervention-specific appendix). The impact on biomarkers, for example, on illness severity or immunological response is dependent on the specific investigational product (also the method and timepoints are dependent on the investigational product). If this will be an outcome parameter, then this will be specified in the intervention-specific appendix of that investigational product. So far, there are no compounds selected for which this will be an outcome parameter.

The study record was updated on 04/01/2023 with the primary outcome measures associated with a prior non-approved protocol version:
Primary study endpoints are dependent on the study phase and can be:
1. Time to first self-report of feeling recovered from symptoms related to COVID-19 or COVID-like illness (days), measured using self-report until the end of the study.
2. Viral clearance assessed using semi-quantitative PCR at baseline and on days 4, 7 and 14, and impact on biomarkers of illness severity (if this will be an outcome parameter, then this will be specified in the intervention-specific appendix). The impact on biomarkers, for example, on illness severity or immunological response is dependent on the specific investigational product (also the method and timepoints are dependent on the investigational product). If this will be an outcome parameter, then this will be specified in the intervention-specific appendix of that investigational product. So far, there are no compounds selected for which this will be an outcome parameter.

Initial primary outcome measure associated with a prior non-approved protocol version:
Primary study endpoints are dependent on the study phase and can be:
1. Time to first self-report of feeling fully recovered from symptoms related to COVID-19 or COVID-like illness (days), measured using self-report until the end of the study
2. Viral clearance assessed using semi-quantitative PCR at baseline and on days 4, 7 and 14, and impact on biomarkers of illness severity (if this will be an outcome parameter, then this will be specified in the intervention-specific appendix). The impact on biomarkers, for example, on illness severity or immunological response is dependent on the specific investigational product (also the method and timepoints are dependent on the investigational product). If this will be an outcome parameter, then this will be specified in the intervention-specific appendix of that investigational product. So far, there are no compounds selected for which this will be an outcome parameter.

Key secondary outcome(s)

The study record was updated on 08/06/2026 with the current primary outcome measures associated with protocol version 7 dated 10/07/2025 to improve readability:
Key secondary outcome: early sustained recovery (recovery by day 14 sustained until day 28)

Other secondary endpoints might include:
1. Sustained recovery (participants' reported recovery that was maintained until 28 days),

captured using a diary, or, if not completed, phone call at 28 days after inclusion
2. Time to first self-report of feeling recovered from symptoms of COVID-19 or COVID-like illness (for Phase IIa type evaluation)
3. Viral clearance measured using semi-quantitative PCR at ISA-specified days (Days 4, 7 and 14 for NONS and saline evaluations; Days 1 and 5 for the LTX-109 evaluation)
4. Reduction in viral load measured using digital PCR from baseline to ISA-specified days (Days 1, 3 and 5 for the LTX-109 evaluation)
5. Time to first self-report of return to usual daily activity.
6. Presence, duration, and severity of individual respiratory symptoms (runny/congested nose, sore throat, cough, fever, shortness of breath, fatigue/tiredness, sweats/chills, headache, muscle, joint and/or body aches, loss of taste/smell, diarrhoea, nausea/vomiting, and others) as absent, mild, moderate, or severe. Captured using a diary or, if not completed, phone calls at 14 and/or 28 days after inclusion.
7. Participant reported overall wellbeing, reported by rating of how well participant feels (scale 0-10) captured using a diary, or, if not completed, phone calls at 14 and/or 28 days after inclusion.
8. Overall safety of the IP by reporting (serious) adverse drug reactions captured using a diary or, if not completed, phone calls at 14 and/or 28 days after inclusion.
9. Tolerability of the IP, via reasons for stopping IP intake captured using a diary or, if not completed, phone calls at 14 and/or 28 days after inclusion.
10. The use of additional antiviral medication (yes/no, name of medication) captured using a diary or, if not completed, phone calls at 14 and/or 28 days after inclusion.
11. The use of other prescribed and/or OTC medication for the respiratory infection (antibiotics, antiviral medication, ibuprofen, other pain/fever medication, inhaled medication, intranasal medication, other) captured using a diary or, if not completed, phone calls at 14 and/or 28 days after inclusion.
12. Impact on usual daily activities (work/education and social life), recorded as: no, slight, moderate, severe, not applicable. Captured using a diary, or, if not completed phone calls at 14 and/or 28 days after inclusion.
13. Complications (hospitalisation, death; all-cause, non-elective hospitalisation) recorded using a diary or, if not completed, phone calls at 14 and/or 28 days after inclusion.
14. Health care utilisation for COVID-19 or COVID-like illness (GP and hospital visits) measured using a diary or, if not completed, phone calls at 14 and/or 28 days after inclusion.
15. The incidence of COVID-19 and COVID-like-illness in other members of the household (using participants' diaries and/or swabbing the symptomatic household member(s)) captured using a diary, or, if not completed, phone calls for 28 days after inclusion
16. Long-term consequences of COVID-19 or COVID-like illness (e.g., cough, shortness of breath and/or difficulty breathing, fast heart rate, fatigue, tiredness and/or loss of energy, sleep alterations, loss of smell and/or taste, emotional sensitivity, depression and/or anxiety, concentration problems and/or difficulty thinking, muscle aches and or generalised body pains, diarrhoea and/or stomach pain, other), captured using a questionnaire, or, if not completed a phone call at 3 months after inclusion

The study record was updated on 13/01/2026 with the key secondary outcome measures associated with protocol version 7 dated 10/07/2025:
1. Sustained recovery, measured using self-report for 28 days
2. Time to first self-report of feeling fully recovered from individual symptoms of COVID-19 or COVID-like illness (days) (for Phase IIa type evaluation), measured using self-report for 28 days (or months 3 and 6 if not recovered).
3. Reduction in viral load
4. Tolerability of the IP
5. IP intake adherence

6. Time to first self-report of return to usual daily activity (days), measured using self-report until the end of the study
7. Presence, duration and severity of individual respiratory symptoms (runny/congested nose, sore throat, cough, fever shortness of breath, fatigue/tiredness, sweats/chills, headache, muscle, joint and/or body aches, loss of taste/smell, diarrhoea, other) as: absent, mild, moderate, severe, measured using a daily diary at days 0-28.
8. Participant-reported overall wellbeing, reported by rating of how well the participant feels (scale 0-10) at day 0-28 and after 3 months
9. Evaluation of the overall safety of the IP by monitoring of AEs for the duration of IP administration and a defined period after the IP administration finishes. The duration of investigational product administration is dependent on the investigational product and will be specified in the intervention-specific appendix, for the selected IPs only side effects will be measured, as safety data are already available.
10. The use of additional antiviral medication (yes/no, name of medication), using a daily diary on days 0-28
11. The use of other prescribed and/or OTC medication for the respiratory tract infection, yes /no, using a daily diary at days 0-28
12. Occurrence of complications (i.e., hospitalisation, death; all-cause, non-elective hospitalisation) measured using weekly diary on days 7, 14, 21 and 28 or Serious Adverse Event reporting during the entire duration of study participation.
13. Impact on usual daily activities (work/education, caring for (grand-)children, household activities, sports, social life), as: no, slight, moderate, severe, not applicable, measured at days 1-28, after 3
14. Healthcare utilisation for COVID-19 or COVID-like-illness (GP and hospital visits) measured using participant diary on days 1-28, months 3
15. Long-term consequences of COVID-19 or COVID-like-illness (e.g. cough, shortness of breath and/or difficulty breathing, fast heart rate, fatigue, tiredness and/or loss of energy, sleep alterations, loss of smell and/or taste, emotional sensitivity, depression and/or anxiety, concentration problems and/or difficulty thinking, muscle aches and or generalised body pains, diarrhoea and/or stomach pain, other) measured using a follow-up call or electronic questionnaire after 3 and 6 months
16. The incidence of COVID-19 and COVID-like-illness in other members of the household, measured using participants' diaries and/or swabbing the symptomatic household member(s) at daily day 0 - 28, if this will be measured using swabs in household members then timepoint(s) will be specified in the intervention-specific appendix

Exploratory parameters:
1. Emergence of mutations in causative pathogens in index cases and potentially in household members measured using combined pharyngeal/nasal swabs for participants swabs that are taken at Day 0 and 4 can be used, if this will be measured in household members then timepoint (s) will be specified in the intervention-specific appendix
2. Experiences of researchers and network coordinators of setting up the trial in multiple countries, including views on optimising trial delivery, recruitment, and implementation (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with researchers and network coordinators will take place throughout the period of ECRAID-Prime prior to trial set-up through to the completion of recruitment and follow-up of patients. We will aim to include longitudinal interviews, interviewing the same participant at multiple timepoints, where possible, to gain insights into how researchers apply learning to improve trial processes throughout the study
3. Healthcare professionals' views and experience of taking part in the trial (in the context of a pandemic), the novel trial design, recruiting patients and views on the intervention(s) (qualitative study) measured using interviews either remotely (by telephone or online or in

person as appropriate). Interviews with healthcare professionals will take place throughout the trial and will focus on key timepoints such as the start of recruitment and the introduction of a new intervention arm.
4. Patient views and experiences of taking part in the trial and trial interventions, including how they conceptualise their illness and recovery (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with patients participating in the trial will take place at a suitable timepoint after their initial consultation (depending on their diagnosis, likely recovery time and the regimen of any trial intervention), likely around 2 weeks, to understand their experience of being recruited to the trial, trial processes, their views of the intervention and intervention adherence (where relevant).

The study record was updated on 23/07/2024 with the key secondary outcome measures associated with protocol version 5 dated 22/03/2024:
1. Sustained recovery, measured using self-report for 28 days
2. Time to first self-report of feeling fully recovered from individual symptoms of COVID-19 or COVID-like illness (days) (for Phase IIa type evaluation), measured using self-report for 28 days (or months 3 and 6 if not recovered).
3. Viral clearance (for Phase IIb and III type evaluation) assessed using semi-quantitive PCR at baseline and on days 4, 7 and 14, and impact on biomarkers of illness severity (if this will be an outcome parameter, then this will be specified in the intervention-specific appendix). The impact on biomarkers, for example on illness severity or immunological response is dependent on the specific investigational product (also the method and timepoints are dependent on the investigational product). If this will be an outcome parameter, then this will be specified in the intervention-specific appendix of that investigational product. So far, there are no compounds selected for which this will be an outcome parameter.
4. Time to first self-report of return to usual daily activity (days), measured using self-report until the end of the study
5. Presence, duration and severity of individual respiratory symptoms (runny/congested nose, sore throat, cough, fever shortness of breath, fatigue/tiredness, sweats/chills, headache, muscle, joint and/or body aches, loss of taste/smell, diarrhoea, other) as: absent, mild, moderate, severe, measured using a daily diary at day 0-28.
6. Participant-reported overall wellbeing, reported by rating of how well participant feels (scale 0-10) at day 0-28, and after 3 months and 6 months
7. Evaluation of overall safety of the IP by monitoring of AEs for the duration of IP administration and a defined period after the IP administration finishes. The duration of investigational product administration is dependent on the investigational product and will be specified in the intervention-specific appendix, for the selected IPs only side effects will be measured, as safety data are already available.
8. The use of additional antiviral medication (yes/no, name of medication), using a daily diary on days 0-28
9. The use of other prescribed and/or OTC medication for the respiratory tract infection, yes/no, using a daily diary at days 0-28
10. Occurrence of complications (i.e. hospitalisation, death; all-cause, non-elective hospitalisation) measured using weekly diary on days 7, 14, 21 and 28 or Serious Adverse Event reporting during the entire duration of study participation.
11. Impact on usual daily activities (work/education, caring for (grand-)children, household activities, sports, social life), as: no, slight, moderate, severe, not applicable, measured at day 1-28, after 3 and 6 months
12. Healthcare utilisation for COVID-19 or COVID-like-illness (GP and hospital visits) measured using participant diary on days 1-28, months 3 and 6
13. Long-term consequences of COVID-19 or COVID-like-illness (e.g. cough, shortness of breath and/or difficulty breathing, fast heart rate, fatigue, tiredness and/or loss of energy, sleep

alterations, loss of smell and/or taste, emotional sensitivity, depression and/or anxiety, concentration problems and/or difficulty thinking, muscle aches and or generalised body pains, diarrhoea and/or stomach pain, other) measured using a follow-up call or electronic questionnaire after 3 and 6 months
14. The incidence of COVID-19 and COVID-like-illness in other members of the household, measured using participants' diaries and/or swabbing the symptomatic household member(s) at daily day 0 - 28, if this will be measured using swabs in household members then timepoint(s) will be specified in the intervention specific appendix

Exploratory parameters:
1. Emergence of mutations in causative pathogens in index cases and potentially in household members measured using combined pharyngeal/nasal swabs for participants swabs that are taken at Day 0, 4, 7 and 14 can be used, if this will be measured in household members then timepoint(s) will be specified in the intervention specific appendix
2. Experiences of researchers and network coordinators of setting up the trial in multiple countries, including views on optimising trial delivery, recruitment, and implementation (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with researchers and network coordinators will take place throughout the period of ECRAID-Prime prior to trial set-up through to the completion of recruitment and follow-up of patients. We will aim to include longitudinal interviews, interviewing the same participant at multiple timepoints, where possible, to gain insights into how researchers apply learning to improve trial processes throughout the study
3. Healthcare professionals’ views and experience of taking part in the trial (in the context of a pandemic), the novel trial design, recruiting patients and views on the intervention(s) (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with healthcare professionals will take place throughout the trial and will focus on key timepoints such as the start of recruitment and the introduction of a new intervention arm.
4. Patient views and experiences of taking part in the trial and trial interventions, including how they conceptualise their illness and recovery (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with patients participating in the trial will take place at a suitable timepoint after their initial consultation (depending on their diagnosis, likely recovery time and the regimen of any trial intervention), likely around 2 weeks, to understand their experience of being recruited to the trial, trial processes, their views of the intervention and intervention adherence (where relevant).

The study record was updated on 03/02/2023 with the key secondary outcome measures associated with a prior non-approved protocol version:
Secondary study parameters/endpoints include:
1. Time to first self-report of feeling fully recovered from symptoms related to COVID-19 or COVID-like illness (days) (for Phase IIa type evaluation), measured using self-report for 28 days (or month 3 and 6 if not recovered).
2. Viral clearance (for Phase IIb and III type evaluation) assessed using semi-quantitive PCR at baseline and on days 4, 7 and 14, and impact on biomarkers of illness severity (if this will be an outcome parameter, then this will be specified in the intervention-specific appendix). The impact on biomarkers, for example on illness severity or immunological response is dependent on the specific investigational product (also the method and timepoints are dependent on the investigational product). If this will be an outcome parameter, then this will be specified in the intervention specific appendix of that investigational product. So far, there are no compounds selected for which this will be an outcome parameter.
3. Time to first self-report of return to usual daily activity (days), measured using self-report until the end of the study

4. Presence and severity of COVID-19 or COVID-like-illness symptoms (runny/congested nose, sore throat, cough, fever shortness of breath, fatigue/tiredness, sweats/chills, headache, muscle, joint and/or body aches, loss of taste/smell, diarrhoea, other) as: absent, mild, moderate, severe, measured using a daily diary at day 0-28.
5. Participant-reported overall wellbeing, reported by rating of how well participant feels (scale 0-10) at day 0-28, and after 3 months and 6 months
6. Possible side effects of the IP measured using a daily diary at day 1-28
7. Evaluation of overall safety of the IP by monitoring of AEs for the duration of IP administration and a defined period after the IP administration finishes. The duration of investigational product administration is dependent on the investigational product and will be specified in the intervention specific appendix, for the selected IPs only side effects will be measured, as safety data are already available.
8. The use of additional antiviral medication (yes/no, name of medication), using a daily diary at day 0-28
9. The use of other prescribed and/or OTC medication for the respiratory infection (antibiotics, antiviral medication, ibuprofen, other pain/fever medication, inhaled medication, intranasal medication, other), yes/no, using a daily diary at day 0-28
10. Impact on usual daily activities (work/education, caring for (grand-) children, household activities, sports, social life), as: no, slight, moderate, severe, not applicable, measured at day 1-28, after 3 and 6 months
11. Complications (i.e. hospitalisation, death) measured using weekly diary at day 7, 14, 21 and 28 or Serious Adverse Event reporting during the entire duration of study participation
12. Healthcare utilisation for COVID-19 or COVID-like-illness (GP and hospital visits) measured using participant diary at day 1-28, months 3 and 6
13. Long-term consequences of COVID-19 or COVID-like-illness (e.g. cough, shortness of breath and/or difficulty breathing, fast heart rate, fatigue, tiredness and/or loss of energy, sleep alterations, loss of smell and/or taste, emotional sensitivity, depression and/or anxiety, concentration problems and/or difficulty thinking, muscle aches and or generalised body pains, diarrhoea and/or stomach pain, other) measured using a follow-up call or electronic questionnaire after 3 and 6 months
14. The incidence of COVID-19 and COVID-like-illness in other members of the household, measured using participants' diaries and/or swabbing the symptomatic household member(s) at daily day 0 - 28, if this will be measured using swabs in household members then timepoint(s) will be specified in the intervention specific appendix

Exploratory parameters:
1. Emergence of mutations in causative pathogens in index cases and potentially in household members measured using combined pharyngeal/nasal swabs for participants swabs that are taken at Day 0, 4, 7 and 14 can be used, if this will be measured in household members then timepoint(s) will be specified in the intervention specific appendix
2. Experiences of researchers and network coordinators of setting up the trial in multiple countries, including views on optimising trial delivery, recruitment, and implementation (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with researchers and network coordinators will take place throughout the period of ECRAID-Prime prior to trial set up through to completion of recruitment and follow-up of patients. We will aim to include longitudinal interviews, interviewing the same participant at multiple timepoints, where possible, to gain insights into how researchers apply learning to improve trial processes throughout the study
3. Healthcare professionals' views and experience of taking part in the trial (in the context of a pandemic), the novel trial design, recruiting patients and views on the intervention(s) (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with healthcare professionals will take place throughout the

trial and will focus on key timepoints such as start of recruitment and introduction of a new intervention arm.
4. Patient views and experiences of taking part in the trial and trial interventions, including how they conceptualise their illness and recovery (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with patients participating in the trial will take place at a suitable timepoint after their initial consultation (depending on their diagnosis, likely recovery time and the regimen of any trial intervention), likely around 2 weeks, to understand their experience of being recruited to the trial, trial processes, their views of the intervention and intervention adherence (where relevant).

The study record was updated on 04/01/2023 with the key secondary outcome measures associated with a prior non-approved protocol version:
Secondary study parameters/endpoints include:
1. Viral clearance (for Phase IIb and III type evaluation)
2. Time to first self-report of return to usual daily activity (days), measured using self-report until the end of the study
3. Presence and severity of COVID-19 or COVID-like-illness symptoms (runny/congested nose, sore throat, cough, fever shortness of breath, fatigue/tiredness, sweats/chills, headache, muscle, joint and/or body aches, loss of taste/smell, diarrhoea, other) as: absent, mild, moderate, severe, measured using a daily diary at day 0-28.
4. Participant-reported overall wellbeing, reported by rating of how well participant feels (scale 0-10) at day 0-28, and after 3 months and 6 months
5. Possible side effects of the IP measured using a daily diary at day 1-28
6. Evaluation of overall safety of the IP by monitoring of AEs for the duration of IP administration and a defined period after the IP administration finishes. The duration of investigational product administration is dependent on the investigational product and will be specified in the intervention specific appendix, for the selected IPs only side effects will be measured, as safety data are already available.
7. Impact on usual daily activities (work/education, caring for (grand-) children, household activities, sports, social life), as: no, slight, moderate, severe, not applicable, measured at day 1-28, after 3 and 6 months
8. Complications (i.e. hospitalisation, death) measured using weekly diary at day 7, 14, 21 and 28 or Serious Adverse Event reporting during the entire duration of study participation
9. Healthcare utilisation for COVID-19 or COVID-like-illness (GP and hospital visits) measured using participant diary at day 1-28, months 3 and 6
10. Long-term consequences of COVID-19 or COVID-like-illness (e.g. cough, shortness of breath and/or difficulty breathing, fast heart rate, fatigue, tiredness and/or loss of energy, sleep alterations, loss of smell and/or taste, emotional sensitivity, depression and/or anxiety, concentration problems and/or difficulty thinking, muscle aches and or generalised body pains, diarrhoea and/or stomach pain, other) measured using a follow-up call or electronic questionnaire after 3 and 6 months
11. The incidence of COVID-19 and COVID-like-illness in other members of the household, measured using participants' diaries and/or swabbing the symptomatic household member(s) at daily day 0 - 28, if this will be measured using swabs in household members then timepoint(s) will be specified in the intervention specific appendix

Exploratory parameters:
1. Emergence of mutations in causative pathogens in index cases and potentially in household members measured using combined pharyngeal/nasal swabs for participants swabs that are taken at Day 0, 4, 7 and 14 can be used, if this will be measured in household members then timepoint(s) will be specified in the intervention specific appendix
2. Experiences of researchers and network coordinators of setting up the trial in multiple

countries, including views on optimising trial delivery, recruitment, and implementation (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with researchers and network coordinators will take place throughout the period of ECRAID-Prime prior to trial set up through to completion of recruitment and follow-up of patients. We will aim to include longitudinal interviews, interviewing the same participant at multiple timepoints, where possible, to gain insights into how researchers apply learning to improve trial processes throughout the study
3. Healthcare professionals' views and experience of taking part in the trial (in the context of a pandemic), the novel trial design, recruiting patients and views on the intervention(s) (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with healthcare professionals will take place throughout the trial and will focus on key timepoints such as start of recruitment and introduction of a new intervention arm.
4. Patient views and experiences of taking part in the trial and trial interventions, including how they conceptualise their illness and recovery (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with patients participating in the trial will take place at a suitable timepoint after their initial consultation (depending on their diagnosis, likely recovery time and the regimen of any trial intervention), likely around 2 weeks, to understand their experience of being recruited to the trial, trial processes, their views of the intervention and intervention adherence (where relevant).

Initial primary outcome measure associated with a prior non-approved protocol version:
Secondary study parameters/endpoints include:
1. Time to first self-report of return to usual daily activity (days), measured using self-report until the end of the study
2. Presence and severity of COVID-19 or COVID-like-illness symptoms (runny/congested nose, sore throat, cough, fever shortness of breath, fatigue/tiredness, sweats/chills, headache, muscle, joint and/or body aches, loss of taste/smell, diarrhoea, other) as: absent, mild, moderate, severe, measured using a daily diary at day 0-28.
3. Participant-reported overall wellbeing, reported by rating of how well participant feels (scale 0-10) at day 0-28, and after 3 months and 6 months
4. Possible side effects of the IP measured using a daily diary at day 1-28
5. Evaluation of overall safety of the IP by monitoring of AEs for the duration of IP administration and a defined period after the IP administration finishes. The duration of investigational product administration is dependent on the investigational product and will be specified in the intervention specific appendix, for the selected IPs only side effects will be measured, as safety data are already available.
6. Impact on usual daily activities (work/education, caring for (grand-) children, household activities, sports, social life), as: no, slight, moderate, severe, not applicable, measured at day 1-28, after 3 and 6 months
7. Complications (i.e. hospitalisation, death) measured using weekly diary at day 7, 14, 21 and 28 or Serious Adverse Event reporting during the entire duration of study participation
8. Healthcare utilisation for COVID-19 or COVID-like-illness (GP and hospital visits) measured using participant diary at day 1-28, months 3 and 6
9. Long-term consequences of COVID-19 or COVID-like-illness (e.g. cough, shortness of breath and/or difficulty breathing, fast heart rate, fatigue, tiredness and/or loss of energy, sleep alterations, loss of smell and/or taste, emotional sensitivity, depression and/or anxiety, concentration problems and/or difficulty thinking, muscle aches and or generalised body pains, diarrhoea and/or stomach pain, other) measured using a follow-up call or electronic questionnaire after 3 and 6 months
10. The incidence of COVID-19 and COVID-like-illness in other members of the household, measured using participants' diaries and/or swabbing the symptomatic household member(s) at

daily day 0 - 28, if this will be measured using swabs in household members then timepoint(s) will be specified in the intervention specific appendix

Exploratory parameters:
1. Emergence of mutations in causative pathogens in index cases and potentially in household members measured using combined pharyngeal/nasal swabs for participants swabs that are taken at Day 0, 4, 7 and 14 can be used, if this will be measured in household members then timepoint(s) will be specified in the intervention specific appendix
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3. Healthcare professionals' views and experience of taking part in the trial (in the context of a pandemic), the novel trial design, recruiting patients and views on the intervention(s) (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with healthcare professionals will take place throughout the trial and will focus on key timepoints such as start of recruitment and introduction of a new intervention arm.
4. Patient views and experiences of taking part in the trial and trial interventions, including how they conceptualise their illness and recovery (qualitative study) measured using interviews either remotely (by telephone or online or in person as appropriate). Interviews with patients participating in the trial will take place at a suitable timepoint after their initial consultation (depending on their diagnosis, likely recovery time and the regimen of any trial intervention), likely around 2 weeks, to understand their experience of being recruited to the trial, trial processes, their views of the intervention and intervention adherence (where relevant).

Completion date
02/07/2026

Eligibility

Key inclusion criteria
The study record was updated on 08/06/2026 with the key inclusion criteria associated with protocol version 7 dated 10/07/2025 to improve readability:
The generic platform inclusion criteria are listed in this section. Potential additional inclusion criteria for specific investigational products will be detailed in the relevant, approved intervention-specific appendix.

In order to be eligible to participate in ECRAID-Prime, a participant must (at least) meet all the following criteria (there can be additional intervention-specific inclusion criteria):
1. Participant is ≥18 years of age on the day of inclusion; if people aged <18 years are suitable for inclusion in the evaluation of an investigational product, then this will be described and justified in the relevant, approved intervention-specific appendix.
2. Presence of at least two symptoms suggestive of COVID-19 or COVID-like illness, one respiratory (cough, sore throat, running or congested nose or sinuses, or shortness of breath) and one systemic (fever, feeling feverish, sweats/chills or shivering, low energy or tiredness, headache, muscle, joint or body aches, or loss of taste and/or smell).

3. Judged by recruiting a medically qualified clinician or delegate that the illness is due to a respiratory infection.
4. Onset of symptoms less than x days (x will be specified in the relevant, approved, intervention-specific appendix).
5. Willing and able to give informed consent for participation in the study.
6. Willing and able to comply with all trial procedures (including availability of freezer at participant's home to store self-collected swabs).
Any additional eligibility criteria relevant to women of child-bearing potential, including current pregnancy or breastfeeding, will be specified in the relevant, approved, intervention-specific appendix

The study record was updated on 13/01/2026 with the key inclusion criteria associated with protocol version 7 dated 10/07/2025:
In order to be eligible to participate in ECRAID-Prime, a participant must (at least) meet all the following criteria (there can be additional intervention-specific inclusion criteria):
1. Participant is ≥18 years of age on the day of inclusion; if people aged <18 years are suitable for inclusion in the evaluation of an investigational product, then this will be described and justified in the relevant, approved intervention-specific appendix
2. Presence of at least two symptoms suggestive of COVID-19 or COVID-like-illness, one respiratory (cough, sore throat, running or congested nose or sinuses, shortness of breath) and one systemic (fever, feeling feverish, sweats/chills or shivering, low energy or tiredness, headache, muscle, joint or body aches, loss of taste and/or smell)
3. Judged by recruiting a medically qualified clinician or research nurse that the illness is due to COVID-19 or COVID-like illness
4. Onset of symptoms less than x days (x will be specified in the intervention-specific appendix)
5. Willing and able to give informed consent for participation in the study
6. Willing and able to comply with all trial procedures
7. Any additional eligibility criteria relevant to women of child-bearing potential, including current pregnancy or breastfeeding, will be specified in the intervention-specific appendix

Previous key inclusion criteria associated with protocol version 5 dated 22/03/2024:
In order to be eligible to participate in ECRAID-Prime, a participant must (at least) meet all the following criteria (there can be additional intervention-specific inclusion criteria):
1. Participant is ≥18 years of age on the day of inclusion; if people aged <18 years are suitable for inclusion in the evaluation of an investigational product, then this will be described and justified in the relevant, approved intervention-specific appendix
2. Presence of at least two symptoms suggestive of COVID-19 or COVID-like-illness, one respiratory (cough, sore throat, running or congested nose or sinuses, shortness of breath) and one systemic (fever, feeling feverish, sweats/chills or shivering, low energy or tiredness, headache, muscle, joint or body aches, loss of taste and/or smell)
3. Judged by recruiting a medically qualified clinician or research nurse that the illness is due to COVID-19 or COVID-like illness
4. Onset of symptoms less than 7 days (in case earlier treatment is required for a specific investigational product, this will be specified in the intervention-specific appendix)
5. Willing and able to give informed consent for participation in the study
6. Willing and able to comply with all trial procedures
7. Any additional eligibility criteria relevant to women of child-bearing potential including current pregnancy or breastfeeding will be specified in the intervention-specific appendix

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
150 Years

Sex
All

Total final enrolment
1021

Key exclusion criteria
The study record was updated on 08/06/2026 with the current key exclusion criteria associated with protocol version 7 dated 10/07/2025 to improve readability:
The generic exclusion criteria are listed in this section. Potential additional exclusion criteria for individual investigational products; for example, specific comorbidities or medication use, will be detailed in the relevant, approved, intervention-specific appendix
A potential participant who meets any of the following criteria will be excluded from participation in ECRAID-Prime:
1. Requiring admission to the hospital on the day of inclusion
2. Known allergies or hypersensitivities to any of the components used in the formulation of the investigational product, the placebo or the comparator investigational product
3. Any disease, condition, or disorder, or language barrier that precludes participation in the trial, in the opinion of the general practitioner (GP) or delegate (with the GP serving as supervisor) checking eligibility and taking consent.
4. Any planned major surgery in the next 28 days
5. Currently participating in a trial of an investigational product
6. Any personnel involved in the study

The study record was updated on 13/01/2026 with the key exclusion criteria associated with protocol version 7 dated 10/07/2025:
A potential participant who meets any of the following criteria will be excluded from participation in ECRAID-Prime (there can be additional intervention-specific exclusion criteria).
1. Requiring admission to the hospital on the day of screening, or inclusion
2. Known allergies or hypersensitivities to any of the components used in the formulation of the investigational product, placebo or the comparator product
3. Any disease, condition, or disorder that precludes participation in the trial, in the opinion of the person checking eligibility and taking consent
4. Any planned major surgery in the next 28 days
5. Currently participating in a trial of an investigational product
6. Any personnel involved in the study

Previous key exclusion criteria associated with protocol version 5 dated 22/03/2024:
A potential participant who meets any of the following criteria will be excluded from

participation in ECRAID-Prime (there can be additional intervention-specific exclusion criteria).
1. Requiring admission to the hospital on the day of screening, or inclusion
2. Known allergies or hypersensitivities to any of the components used in the formulation of the investigational product, or the control product
3. Any disease, condition, or disorder that precludes participation in the trial, in the opinion of the person checking eligibility and taking consent
4. Any planned major surgery in the next 28 days
5. Currently participating in a trial of an investigational product

Date of first enrolment
03/10/2024

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
United Kingdom

Belgium

France

Georgia

Germany

Ireland

Poland

Spain

Study participating centre
Nuffield Department of Primary Care Health Sciences, University of Oxford
Gibson Building 1st floor
Radcliffe Observatory Quarter
Woodstock Road
Oxford
England
OX2 6GG

Study participating centre
Honiton Surgery
Marlpits Lane
Honiton

England
EX14 2NY

Study participating centre
Melrose Surgery
73 London Road
Reading
England
RG1 5BS

Study participating centre
Bovey Tracey and Chudleigh Medical Practice
Riverside Surgery, Le Molay, Littry Way
Bovey Tracey
England
TQ13 9QP

Study participating centre
Banbury Cross Health Centre
South Bar House
6 Oxford Road
Banbury
England
OX16 9AD

Study participating centre
St. Bartholemews Medical Centre
Manzil Way
Oxford
England
OX4 1XB

Study participating centre
Bicester Health Centre
The Health Centre
Coker Close
Bicester
England
OX26 6AT

Study participating centre
Gosford Hill Medical Centre
167 Oxford Road
Kidlington
England
OX5 2NS

Study participating centre
The White Horse Medical Practice
The Faringdon Medical Centre
Volunteer Way
Faringdon
England
SN7 7YU

Study participating centre
Hedena Health
207 London Road
Headington
Oxford
England
OX3 9JA

Study participating centre
Huisartsenpraktijk Pairon Muyldermans
-
Schilde
Belgium
2970

Study participating centre
Artsenpraktijk Waarloos
Grote Steenweg 47
Kontich
Belgium
2550

Study participating centre
Medisch Huis Ter Linden
Strijdersstraat 20

Edegem
Belgium
2650

Study participating centre
Hausärztliche Gemeinschaftspraxis Jung/Marold/Beetz
Hauptstraße 12
Gössenheim
Germany
97780

Study participating centre
CAP Mas Font
Passeig de la Marina, 2
Viladecans, Barcelona
Spain
08840

Study participating centre
CAP Alhambra
C/ de l'Alhambra, 20
L'Hospitalet de Llobregat, Barcelona
Spain
08902

Study participating centre
CAP Vila Vella
Carretera de Sant Boi, 0
Sant Vicenç dels Horts, Barcelona
Spain
08620

Study participating centre
GPs at Tallaght Cross
3rd Floor, Russell Centre, Tallaght Cross West
Tallaght, Dublin 24
Ireland
D24DH74

Study participating centre
Huisartsenpraktijk Zwaantjes
Antwerpsesteenweg 454
Hoboken
Belgium
2660

Study participating centre
Wijkgezondheidscentrum De Vlier
Truweelstraat 114
Sint Niklaas
Belgium
9100

Study participating centre
Huisartsenpraktijk Brig
Robert Vekemansplein 3 bus 1
Boom
Belgium
2850

Study participating centre
Huisartsenpraktijk Wolvenberg
Vreestraat 93
Berchem
Belgium
2600

Study participating centre
Praktijkhuis de Grote Rivier
Lanteernhofstraat 106
Deurne
Belgium
2100

Study participating centre
Huisartsenpraktijk Lange Leem
Lange Leemstraat 385
Antwerpen
Belgium
2018

Study participating centre
University Hospital Würzburg
Josef-Scheneider-Strasse 2
Wurzburg
Germany
97080

Study participating centre
CAP Jaume I
C/Jaume I, N45-49
Tarragona
Spain
43005

Study participating centre
Cap 17 de setembre
Cl empúries, 1-3
Prat de Llobregat
Spain
8820

Study participating centre
CAP Sant Marti de Provencals
Calle fluvia, 211
Barcelona
Spain
8020

Study participating centre
CAP Maresme
Camino Del Mig N 36
Mataro
Spain
8303

Study participating centre
CAP Sardenya
Carrer de Sardenya 466

Barcelona
Spain
8025

Study participating centre
Centre d'Ivestigation Clinique CHU de Limoges
2 avenue Martin Luther King
Limoges Cedex 1
France
87042

Study participating centre
Crescent Medical Centre
1 The Crescent
Galway
Ireland
H91EFP

Study participating centre
Heights Medical Centre
Castlawn Heights, Coolough Road
Galway
Ireland
-

Study participating centre
Main Street Clinic
Main Street
Loughrea
Ireland
H62X252

Study participating centre
Moyview Family Practice
Dillon Terrace
Ballina
Ireland
F26R9V2

Study participating centre
Tramore Medical Centre
Summerhill
Tramore
Ireland
X91PK5E

Study participating centre
Akademicka Praktyka Medycyny Rodzinnej Bielska
Ul. Mazowiecka 33
Bialystok
Poland
15-301

Study participating centre
Medimed
Ul. Juliana Tuwima 1/2 Lok 2
Bialystok
Poland
15-746

Study participating centre
Spólka cywilna SILOE katarzyna Jachimowicz
W. Raginisa 87/2
Bialystok
Poland
15-161

Study participating centre
Poradnia Lekarza Rodzinnego Joanna Redzko-Baszun
Klepacka 4
Bialystok
Poland
15-634

Study participating centre
Centrum Medyczne Kleosin Wieliczko
Ul. Zambrowska 14, Kleosin
Juchnowiec Koscielny
Poland
16-001

Study participating centre
Medcapital LLC
18 Vekua St
Tbilisi
Georgia
0167

Sponsor information

Organisation
University Medical Center Utrecht

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Government

Funder Name
European Union

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 08/06/2026:
The full protocol, e-CRF template and other relevant trial materials will be made openly available via the ECRAID-Prime community on Zenodo (EU Open Research Repository). Participant-level data will be made available upon reasonable request once the primary analysis has been published.

Previous IPD sharing plan:
Descriptive metadata will be made fully open through a cohort browser. Controlled access, participant-level data will be made available through a controlled access data platform. Restricted access, participant-level data will be made available to internal partners (e.g., statisticians at participating institutions) within the ECRAID-Prime internal network through the UMCU data warehouse infrastructure. Restricted access participant-level data that includes individual identifiers (e.g., birth date) will not be made openly accessible in line with national,

European and international legal, ethical and privacy concerns and to ensure that data sharing complies with the GDPR.

IPD sharing plan summary

Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0	22/03/2024	09/10/2024	No	No
Protocol file	ISA A version 4.0	22/03/2024	09/10/2024	No	No
Protocol file	ISA B version 4.0	22/03/2024	09/10/2024	No	No
Protocol file	ISA C version 4.0	22/03/2024	09/10/2024	No	No
Protocol file	version 7.0	10/07/2025	08/06/2026	No	No
Protocol file	ISA A Version 6.0 version 6.0	10/07/2025	08/06/2026	No	No
Protocol file	ISA B Version 6.0 version 6.0	10/07/2025	08/06/2026	No	No
Protocol file	ISA C Version 6.0 version 6.0	10/07/2025	08/06/2026	No	No
Protocol file	ISA D Version 1.0 version 1.0	22/04/2025	08/06/2026	No	No
Protocol file	ISA A UK specific V1.0 version 1.0	25/09/2025	16/06/2026	No	No
Protocol file	ISA B UK specific V1.0 version 1.0	25/09/2025	16/06/2026	No	No
Protocol file	ISA C UK specific V1.0 version 1.0	25/09/2025	16/06/2026	No	No
Protocol file	Protocol UK specific V1.0 version 1.0	25/09/2025	16/06/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes