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SARS-CoV-2 vaccination for COVID-19 disease safety study

Submission date
03/12/2020

Recruitment status
No longer recruiting

Registration date
21/12/2020

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
This is an online study created by MEMO (Medicines Monitoring Unit) Research at the University of Dundee to track any vaccines that are being used to prevent COVID-19 infection. All vaccines are tested for safety and effectiveness on human volunteers in large clinical trials. There are some things that we can only find out once vaccines are being used widely. Initially launching in the UK, and expanding to more countries around the globe, this study will track vaccines to check they are working well. It will be big enough to detect any rare unexpected vaccine side effects. Participation in this study is voluntary and it will not interfere with normal care from participants' GP practices.

Who can participate?
Patients aged 18 or older who have access to a desktop computer, laptop or smartphone or tablet device, and who have a valid unique email address that only they use.

What does the study involve?
Participants sign up to a secure website and consent to take part both before and after they are vaccinated. They provide information about themselves (e.g. demographics, past medical history, medication) and then receive reminder emails monthly (or weekly for 4 weeks after they

receive a vaccination or booster) asking them to provide information about their health and wellbeing. Any events of interest will be followed up with the participant, their emergency contact and/or their healthcare professionals.

What are the possible benefits and risks of participating?
There is no immediate benefit for the participants, but they will be contributing to improving the knowledge about the safety and effectiveness of COVID-19 vaccinations.

Where is the study run from?
University of Dundee (UK)

When is the study starting and how long is it expected to run for?
June 2020 to December 2023

Who is funding the study?
University of Dundee (UK)

Who is the main contact?
Wendy Saywood
vac4covid@dundee.ac.uk

Study website
https://www.vac4covid.com

Contact information

Type(s)
Scientific

Contact name
Ms Wendy Saywood

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
286051

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 286051

Study information

Scientific Title
SARS-CoV-2 Vaccination for COVID-19 Disease Safety Study (VAC4COVID Study): a prospective, active observational, post-authorisation surveillance safety study (PASS) of vaccines for COVID-19 disease

Acronym
VAC4COVID

Study objectives
The aim of the study is to monitor the safety and effectiveness of COVID-19 vaccines by gathering information from a large number of participants about their health before and after they are vaccinated. We will do this by collecting health information from study participants. Participants will provide information before and after vaccination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/01/2021, NHS Berkshire B Committee (Reading Business Centre, Fountain House, 2 Queens Walk, Reading, Berkshire, RG1 7QF, UK; +44 (0)207 1048226; berkshireb.rec@hra.nhs.uk), ref: not provided

Study design
Prospective active observational post-authorisation surveillance safety study (PASS)

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
https://www.vac4covid.com

Health condition(s) or problem(s) studied
Safety monitoring for all COVID-19 (SARS-CoV-2 infection) vaccinations

Interventions
Participants will be recruited pre and post COVID-19 vaccination and will include people who decide not to be vaccinated. It is an online, observational study where patients fill in initial health and demographic information, details of their vaccination and then complete regular follow-ups recording any serious adverse events. Everything will be done online on a secure website. Follow up will be for at least 1 year but can be extended if required by regulatory authorities or the Sponsor.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
BNT162b2 vaccine (Pfizer-BioNTech) ChAdOx1 vaccine (AstraZeneca vaccine)

Primary outcome measure
SAEs reported by participants, emergency contacts and healthcare professionals both prior to and after vaccination for the whole vaccinated and unvaccinated population, as well as for predefined subgroups, during the study observation period. Special attention will be given to AESI, updated lists of which may be produced by regulators/health authorities during the study based on the most recent updates regarding vaccine development and safety.

Secondary outcome measures
Reported by participants, healthcare professionals, medical records (including written and electronic records, and national databases, where possible), and emergency contacts during the study observation period:
1. Adverse events prior to and after vaccination for the whole vaccinated and unvaccinated population and in predefined subgroups
2. All-cause mortality rate for the whole study population and predefined subgroups
3. Rates and severity of participant-reported symptomatic COVID-19 infection in vaccinated and unvaccinated cohorts
4. Reported reasons for non-vaccination

Overall study start date
22/06/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over (participants with primary caring responsibilities for children under the age of 18 may submit information on the child’s behalf with age-appropriate agreement)
2. Valid email address (per adult participant) and able to access and use the internet
3. Subjects willing to nominate at least one, preferably two, emergency contact(s)

Participant type(s)
All

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
20,000

Total final enrolment
21104

Key exclusion criteria
1. No access to internet enabled devices to enable participation
2. Unable to consent due to incapacity
3. Unwilling or unable to nominate at least one emergency contact

Date of first enrolment
03/02/2021

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
University of Dundee
MEMO Research
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee

Sponsor details
TASC
Ninewells Hospital
Dundee
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United Kingdom
DD1 9SY
+44 (0)138 383297
tascgovernance@dundee.ac.uk

Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
University/education

Funder Name
University of Dundee

Alternative Name(s)
Dundee University, Oilthigh Dhùn Dè

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. A paper relating to the study protocol will be published in a peer-reviewed journal during the course of the study
2. Planned publication in a high impact, peer-reviewed journal and presented at an international research meeting

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan
Current participant level data sharing statement as of 17/01/2025:

The dataset will be stored within a user-access controlled database on the MEMO Research server which is part of the University of Dundee secure servers. At the end of the study, it will be archived according to UoD guidelines and accessible on request to Professor I.M.Mackenzie (vac4covid@dundee.ac.uk), for the purpose of audit and regulatory inspection. The analysed data will be part of the publication of the results at the end of the study. Individual-level data will not be made available to ensure that anonymity is maintained.

Participants consented to their submitted data being analysed in this way with no individual data being released to avoid identification. Any research group wishing to use the data should apply to the Steering Committee who will have to approve the proposal and ensure that there are no data breaches.
Data will be archived for 5 years after the end of the study (31/12/2028).

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Previous participant level data sharing statement:

The dataset will be stored within a user-access controlled database on the MEMO Research server which is part of the University of Dundee secure servers. At the end of the study, it will be archived according to UoD guidelines and accessible on request for the purpose of audit and regulatory inspection. The analysed data will be part of the publication of the results at the end of the study. Individual-level data will not be made available to ensure that anonymity is maintained.

IPD sharing plan summary
Available on request, Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Adverse events and overall health and well-being after COVID-19 vaccination results	01/06/2022	08/06/2022	Yes	No