ISRCTN45343680 https://doi.org/10.1186/ISRCTN45343680

Impact of rapid diagnostic tests for capillary C-reactive protein (CRP) on antibiotic use in general medicine

Submission date
12/09/2024

Recruitment status
Not yet recruiting

Registration date
24/09/2024

Overall study status
Ongoing

Last Edited
24/09/2024

Condition category
Respiratory

[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
According to the WHO, antibiotic resistance is on the increase worldwide. According to the European Surveillance of Antimicrobial Consumption Network (ESAC net), France is one of the leading prescribers of antibiotics in Europe, well above the European average, with a defined daily dose of 28.5, compared with the European average of 21.9. According to INSERM, one way of combating antibiotic resistance would be to use inexpensive, easy-to-use rapid tests. C-reactive protein (CRP) is a protein produced by the liver as a result of inflammation or infection in the body and rises rapidly in the blood. It is measured to give an idea of the likelihood of infection. CRP is often high in bacterial infections and low in viral infections. CRP is usually measured by taking a blood sample, but the result is not immediate. There is now an automated system for rapid CRP analysis (5 minutes), using a capillary sample taken from a drop of blood from the fingertip. This rapid assay could reduce the need for antibiotics and complementary tests, and help guide prescriptions. In practice capillary CRP is performed, for example, in the event of prolonged fever with no obvious clinical signs, to determine whether or not antibiotics should be prescribed. It can also be carried out when there is doubt as to whether a viral infection does not require an antibiotic prescription or a bacterial infection does. This study was designed by Clermont Ferrand's General Practice Department to evaluate in real conditions this biological device. The study evaluates to what extent the CRP capillary assay reduces antibiotic prescriptions in primary care patients in medical practices with upper and lower respiratory infections. The secondary objectives aim to evaluate the medico-economic and psychological impacts of the use of the assay.

Who can participate?
Patients of all ages over 3 months old with respiratory infections in primary care

What does the study involve?
In this study, 84 GPs will be split into two groups through random assignment. The intervention group will receive CRP test machines for 12 months. The GPs in this group will use the CRP test on patients with respiratory infections. The control group will not receive the machines and will continue with their usual practice, without using the CRP tests. The study will include 4,200

patients in total, with 2,800 patients with lower respiratory infections (such as bronchitis or pneumonia) and 1,400 in the intervention group who will receive the CRP test. It will involve, 1,400 patients with upper respiratory infections (such as ear infections or sore throats), with 700 in the intervention group who will also receive the CRP test. The control group GPs will treat their patients without using the CRP test.

What are the possible benefits and risks of participating?
The possible benefits of participating are better diagnosis in primary care, less uncertainty, and combating collective and personal antibiotic resistance. There is no risk from providing the capillary sample.

Where is the study run from?
The sponsor is the Maison de santé des Batignolles, a healthcare establishment with a FINESS number (630012284) that promotes research. Clermont Auvergne University is the guarantor and supporter of the research project.

When is the study starting and how long is it expected to run for?
September 2023 to September 2026

Who is funding the study?
Clermont Auvergne University

Who is the main contact?
Prof Amélie Richard, amelie.richard@uca.fr

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Amelie Richard

ORCID ID
http://orcid.org/0000-0001-9813-6632

Contact details
University of Clermont Auvergne
28 Place Henri Dunant
Clermont Ferrand
France
63 000
+33 06 460 01 79 77
amelie.richard@uca.fr

Additional identifiers

EudraCT/CTIS number
NIl known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of CRP testing in primary care centers to reduce antibiotics use in respiratory infection: a randomized controlled trial

Acronym
ACROPOLE

Study objectives
Does using the capillary test for C-reactive protein levels reduce antibiotic prescriptions for respiratory infections in general practice?

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 10/09/2024, Personnal protection commitee sudest 6 (Hospital Center 28 Rue Henri Dunant, Clermont Ferrand, 63000, France; +33 0473751073; cpp-sudest6@chu-clermontferrand.fr), ref: 1010

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Care home, GP practice, Medical and other records

Study type(s)
Diagnostic, Treatment, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Combating the misuse of antibiotics in patients with respiratory infections in primary care

Interventions
A total of 84 GPs will be recruited and assigned in two groups, through randomization by the biostatistician. Half of the investigators will form an « intervention group » and will receive CRP test machines made available for 12 months. Capillary CRP machines enable CRP to be measured by capillary test in 5 minutes.
The intervention group's investigators will systematically perform a CRP capillary test on the patients included in the study. The other half of the GPs will form a «control group » and will not use CRP capillary tests during their consultations.
The participation of 2800 patients with lower respiratory tract infections (bronchitis, pneumonia, chronic obstructive pulmonary disease exacerbation, flu), will be needed. 1400 patients will be enrolled in the intervention group and will have CRP capillary test.
The participation of 1400 patients with higher respiratory tract infections (otitis, rhinopharyngitis, tracheitis and laryngitis) will be needed. 700 will be enrolled in the intervention group and will have a CRP capillary test.
Physicians in the control group will not have capillary CRP machines and work as usual.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Capillary CRP diagnostic test

Primary outcome measure
The correlation between capillary CRP levels measured in mg/L using the capillary CRP diagnostic test in the intervention group and the antibiotic prescription rate in the control group measured using data collected from medical records one month after the consultations

Secondary outcome measures
The following secondary outcome measures are measured using data collected in a questionnaire one month after the consultation:
1. The medico-economic impact: the number of consultations (GPs, specialists and Emergency service) in the month following the first consultation and their prices, antibiotics prescriptions and their prices, other treatments prescribed and their prices, cost of medical leaves prescription, cost of radiology exams prescription
2. The ecological-bacterial impact: the number of broad-spectrum antibiotics (fluoroquinolone, amoxicillin-clavulanic acid, 3rd generation cephalosporin)
3. The medical impact: the time to heal
4. The psychological impact: patients in the intervention group only and GP's opinions about the use of CRP capillary-test, confidence in the medical decision, advantage perceived by the patient with CRP capillary test

Overall study start date
10/09/2023

Completion date

10/09/2026

Eligibility

Key inclusion criteria
1. 3 months of age or older
2. At least one of the following symptoms: cough, rhinorrhea, blocked nose, dyspnea, mucopurulent discharge, fever, general state alteration with aches, asthenia

Participant type(s)
Patient, Health professional

Age group
Mixed

Lower age limit
3 Months

Upper age limit
99 Years

Sex
Both

Target number of participants
84 GP, 4200 patients

Key exclusion criteria
1. Pregnant women
2. Persons under guardianship
3. Infection without respiratory signs (digestive or urinary infection)
4. Sore throat (because quick test StreptoTest is available)
5. Withdrawal of consent

Date of first enrolment
01/09/2025

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
France

Study participating centre
Health Centre Les Batignolles
4 impasses des Batignolles

Joze
France
63350

Sponsor information

Organisation
Les Batignolles University Multi-disciplinary Health Center

Sponsor details
4 Impasse des Batignolles
Joze
France
63350
+33 04 73 28 00 10
catherine.laporte2@uca.fr

Sponsor type
Hospital/treatment centre

Website
https://www.maisondesantejoze.fr/

Funder(s)

Funder type
University/education

Funder Name
Université Clermont-Auvergne

Alternative Name(s)
University of Clermont Auvergne, Clermont Auvergne University, Universidad Clermont Auvergne, , UCA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
France

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/09/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (https://drive.uca.fr/library/d55ce12e-33ae-4f44-b63b-83e125973865/crp%20capillaire%20Bruno%20Santoro/). The datasets will be available upon request from Prof Amélie Richard, amelie.richard@uca.fr. The type of data that will be shared: anonymized CRP values table in Excel. The data will become available at the beginning of the study (2025) and for 10 years. The data will be anonymised, and names are replaced by numbers as participants are included. Each center also receives a number. Consent is required; non-consent is a disqualifying factor. No ethical or legal restrictions.

IPD sharing plan summary
Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/09/2024	No	Yes