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Carbon monoxide screening in ED patients with headache

Submission date
23/09/2025

Recruitment status
Recruiting

Registration date
08/12/2025

Overall study status
Ongoing

Last Edited
08/12/2025

Condition category
Injury, Occupational Diseases, Poisoning

[ ] 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
Carbon monoxide (CO) exposure is an important but often overlooked cause of headaches. Many patients who come to the emergency room with headaches are not routinely checked for CO exposure, and how common it is or which patients are most at risk is not fully understood. Being better at recognising headaches caused by CO could help doctors diagnose the problem earlier, stop people from being exposed to more CO, and prevent long-term brain and health issues. Low-level CO exposure often goes unnoticed, especially indoors, where appliances like boilers or fireplaces may not be working properly or may lack good ventilation. People exposed to these low levels of CO repeatedly often have headaches that do not have an obvious cause, but improve once they are away from the source of CO.

To find out how often CO exposure causes headaches, two main methods have been used: testing CO levels in the blood and checking for sources of CO in a person's environment. During this study, CO levels will be measured in patients coming to the emergency room with headaches using two methods: a quick, non-invasive finger sensor called CO-oximetry, and a standard blood test. The finger sensor gives fast results without needing a blood sample, and research suggests it can be useful in emergency settings. It might also be cheaper and easier to use, especially in places where blood tests aren't always possible. Since CO leaves the blood quickly, this quick test could be more effective at catching recent exposure. The study will also collect information about the patients' environments to see if they are exposed to CO at home. Previous research found that many people do not have CO alarms or are not aware that they do, which puts them at risk of undetected CO exposure. To help track this, a portable CO monitor will be given to each patient to take home for one week. These monitors detect much lower levels of CO than regular alarms.

This study aims to evaluate the feasibility, acceptability, and operational practicality of the one-week home CO monitoring in identifying environmental CO exposure. It will also explore the number of patients attending the Emergency Department (ED) with a simple headache who have been exposed to carbon monoxide, as well as assessing the agreement between different CO measurement methods (blood tests, CO-oximetry, and home monitoring) and how they relate to patient symptoms. The team will also assess the impact of the time of year on CO exposure in homes, and recruitment, retention, data completeness, and participant adherence

information will also be analysed. This will lead to the development of draft clinical guidance for identifying and managing CO exposure in patients with headache, suitable for future testing in further research.

Who can participate?
Adult patients aged 18 and over attending the ED with a headache, but are unlikely to be admitted to the hospital.

What does the study involve?
The study is made up of various data collection points outlined below:
During ED visit - Baseline (Day 0):
Whilst in ED, patients will receive two procedures to measure the carbon monoxide levels in their blood (known as carboxyhaemoglobin, or COHb). The first procedure is a routine test that would take place within usual care, which involves a member of the clinical team taking a blood sample and processing it using a device known as a blood gas machine. The second procedure involves a painless finger probe test, where a device will be placed on the tip of a finger to measure COHb levels. Before the participant is discharged from ED, a member of the research team will provide them with a transportable carbon monoxide alarm and instructions on how to use it. All participants will receive a stamped, addressed envelope to return the monitor to the research team after 7 days.

7-day home monitoring phase, post-discharge:
After discharge, the 7-day home monitoring period will begin. Participants will be asked to put the carbon monoxide alarm in their kitchen, as far as possible from the boiler/stove. Participants will receive a daily message or email from the research team each evening with a link to the daily home monitoring questionnaire measuring symptoms, alongside a paper copy.

Day 8:
Participants will be asked to return the monitor to the research team using the stamped, addressed envelope provided. Participants will be given an optional £10 bank transfer upon the return of the monitor.

Day 14 follow-up (± 7 days):
The research team will follow up at 14 days post-discharge to recheck symptoms. If the CO monitor has been received, participants will get the results of the 7-day home monitoring period, and if high levels of CO are detected, they will receive information on corrective measures and may be referred to the National Emergency Gas Service.

[OPTIONAL] CO monitoring follow-up:
For patients who return their CO monitor later than day 14, participants will receive a follow-up telephone call after the symptom check to provide results.

Day 42 follow-up (± 7 days):
All participants will receive a final follow-up at 6 weeks (± 7 days) to recheck symptoms. If the research team detects abnormal levels of CO during the analysis, they will take note of any corrective measures made by participants.

What are the possible benefits and risks of taking part in this study?
The information obtained from this study will help the research team to understand if the study method is feasible among patients with headaches in the ED. This will then inform a larger main trial across multiple centres.

The study will be beneficial to people who have high environmental CO levels recorded, as it will highlight the potential cause of headaches and enable participants to take corrective actions.

There are no anticipated risks or disadvantages to taking part in this study.

Where is the study run from?
St George’s Emergency Department Collaborative Research Group, St George's University Hospitals NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
September 2025 to June 2027

Who is funding the study?
The CO Research Trust (CORT), UK

Who is the main contact?
Kathryn Willis (study co-ordinator), EDCOstudy@stgeorges.nhs.uk

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
335774

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 59081

Study information

Scientific Title
Screening for low-level carbon monoxide exposure in patients attending the Emergency Department with headache

Acronym
EDCO-H

Study objectives
Primary objectives:
To evaluate the feasibility, acceptability, and operational practicality of one-week home CO monitoring in identifying environmental CO exposure

Secondary objectives:
To determine the proportion of patients presenting to Emergency Departments with simple headache who have been exposed to carbon monoxide.

To assess the agreement between CO levels measured through blood tests, CO-oximetry, and home monitoring, and their correlation with screening questionnaire responses and patient-reported symptoms

To characterise levels and temporal variations in CO exposure in homes

To assess recruitment, retention, data completeness, and participant adherence to study procedures

To develop draft clinical guidance for identifying and managing CO exposure in patients with headache, suitable for future testing in primary care, EDs, and headache clinics

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending submission

Study design
Single-centre longitudinal observational and feasibility study

Primary study design

Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Carbon monoxide screening in ED patients with headache

Interventions
The data collected in this study will be pseudoanonymised and all participants will be assigned a unique identification (ID) number. The clinical research team at the hospital will have access to a data key that links the unique ID number to the participant's medical record number. This will be accessed only by the clinical research team and held on password-protected servers at the local site.

1. Screening assessment
All patients attending the Emergency Department will undergo routine clinical assessment, including clinical judgment, blood test measurement and further investigations as per standard practice at the hospital. This information will be used to determine if patients meet the study eligibility criteria.

2. Baseline COHb assessment
Eligible participants will be consented before study procedures. All patients considered eligible for the study will have blood drawn as part of routine care in the Emergency Department. This test, known as a venous blood gas, includes COHb measurement and as such, this test is not considered a study procedure. The routinely collected results will be recorded. As near simultaneously as taking the blood sample, the participant will have their CO-oximetry level recorded. This is a device that uses a finger-probe to non-invasively measure CO in the bloodstream. It is not routinely used in ED care but might provide an alternative to blood testing of COHb where this is not available.

3. Data collection – ED attendance
Following CO measurements and at an appropriate time whilst in the ED, participants will be guided by research staff through an electronic questionnaire to capture information including demographic characteristics (age, socioeconomic status, ethnicity), smoking status, headache and associated symptoms, and ED attendance information. Participants will be asked specific CO screening questions in line with UK guidance:

C – Cohabitees/companions – Is anyone else in the property affected (including pets)?
O – Outdoors – Do your symptoms improve when out of the building? (‘better outdoors’)
M – Maintenance – Are your fuel-burning appliances and vents properly maintained?
A – Alarm – Do you have a carbon monoxide alarm?

Additional information on the patient disposition from the ED and their diagnosis will be recorded by the clinical research team from the electronic medical record (EMR).

4. Environmental CO monitoring
A key feature of this study is the linking of environmental CO data with the participant’s clinical information. To achieve this, participants will be given a portable ambient CO monitor at hospital discharge for 1 week. Participants will be given instructions on the placement of this in their home. All participants will be given the study coordinator's contact details in case of any

questions during the data collection period. Participants will also be provided with a stamped, addressed envelope to return the CO monitor to the research team following data collection. Feasibility will be assessed through monitor return rates, diary completion rates, and participant-reported usability and burden.

A study coordinator will contact all participants at day 14-post-discharge to recheck symptoms and, where possible, provide results of their environmental monitoring within one week of the return of the CO monitor. Those who are identified as having a raised CO level will be advised on the need to seek further medical treatment and on identifying/rectifying issues in their homes in line with current guidance from the NHS, gas distribution services, and the UKHSA (UKHSA, 2022).

As part of environmental monitoring, participants will be asked to complete an online survey every day for 7 days to assess any potential symptoms experienced by themselves or other household residents. Headache characteristics will also be recorded. This will identify any distinguishable characteristics of headaches in patients with CO exposure. No geographical data or live locations can be recorded by the devices. The online survey will be sent to participants automatically using the Gather database via text message, and participants will also consent to being contacted by the research team to remind them to complete their data if the research team notices that it has not been completed. The option of completing paper questionnaires will be available to patients who would prefer this method, but online data collection should be advised as the preferred method of data collection, as this removes the risk of transcription error of source data. eCRFs also increase the likelihood of completion due to the capability to send electronic reminders.

5. CO monitor results follow-up
All participants will be contacted by the study coordinator within 1 week of the return of the monitoring device to inform them of the results. This includes those who have no CO detected, as the researchers are aware that 'not knowing' may produce anxiety. Participants with suspected CO exposure will be contacted by the study coordinator at relevant points to enquire about the outcome of any remedial work done by gas engineers and any resolved or ongoing symptoms. Participants with ongoing symptoms will be advised to contact their GP.

6. Day 42 follow-up
All participants will receive a follow-up telephone call with a member of the research team at 6 weeks post-discharge (± 7 days) to recheck symptoms and, if the participant had raised CO level, the results of any gas engineer checks or remedial work.

7. Safety follow-up
Patients who are suspected to have been exposed to CO at any point during the study or have defective appliances or heating at home will be given CO safety advice in line with national guidance and offered instructional support on how to contact gas engineers. Suspected CO exposure will be defined as the following:
- Raised COHb at hospital visit
- Clinical suspicion of CO documented in medical records
- Positive to either COMA_C or COMA_O
- High levels of CO in environmental monitoring

Intervention Type
Other

Primary outcome(s)

Feasibility of the methodology will be measured by assessing the number of eligible versus enrolled patients, the data completeness from participants and the withdrawal/non-complete rates collected from study records throughout the trial and at the study endpoint

Key secondary outcome(s))
1. The proportion of patients presenting to Emergency Departments with simple headaches who have been exposed to carbon monoxide (percentage), measured using data collected from study records at baseline.
2. The agreement between CO levels measured through blood tests, CO-oximetry, and home monitoring, and their correlation (comparative statistics) with screening questionnaire responses at baseline and patient self-reported symptoms measured using a questionnaire involving headache characteristics and CO poisoning symptoms during the 7-day monitoring period, and at days 14 and 42 post-discharge.
3. Prevalence and symptoms during different seasons will be used to characterise levels and temporal variations in CO exposure in homes. This will be measured using environmental CO data collected during the 7-day monitoring period, with a comparison of positive results across different times of year.
4. Recruitment, retention, data completeness, and participant adherence to study procedures (percentage) measured using comparison of the number of participants who are approached (screening), the number of participants who enrol into the study (baseline) and the number of patients who complete all study procedures (day 42 follow-up).

Completion date
01/06/2027

Eligibility

Key inclusion criteria
1. 'Walk in' adult patients ≥ 18yrs
2. Presenting with symptoms of headache (either as the main symptom or as part of a cluster of symptoms). This includes patients with suspected CO exposure.
3. Willing and able to give informed consent for participation in the study
4. Willing and able to return the study CO monitor within 5 days of the end of the CO monitoring period
5. Likely to be discharged from the ED

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Children under the age of 18 years
2. Headache precipitated by another condition, e.g. head trauma or stroke
3. Clinical condition warranting immediate or urgent medical assessment
4. Patients lacking the capacity to provide informed consent

Date of first enrolment
01/12/2025

Date of final enrolment
01/05/2027

Locations

Countries of recruitment
United Kingdom

England

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St Georges University Hospitals NHS Foundation Trust
Blackshaw Road
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Sponsor information

Organisation
St George’s University Hospitals NHS Foundation Trust

ROR
https://ror.org/039zedc16

Funder(s)

Funder type

Research organisation

Funder Name
CO Research Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date