

The ED-CO study: screening for carbon monoxide exposure in the emergency department

Submission date 13/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/11/2019	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 03/01/2024	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Carbon monoxide (CO) is a poisonous gas that can be produced when fuels are not completely burned. Breathing in CO can cause death, but at low levels of exposure, it can cause headaches, dizziness, tiredness, confusion, stomach pain and shortness of breath. CO cannot be seen or smelt, so it can make people ill without them being aware that they have been exposed to it. It is not known how common exposure to CO is in England. Doctors and nurses may not realise that a person's illness is because they have breathed in CO because the symptoms are similar to symptoms of other illnesses, such as flu. There is also some evidence that exposure to CO might be linked to dementia. The aim of this study is to investigate whether people who come to Accident & Emergency (A&E) with these symptoms have breathed in CO. The study will also investigate whether a set of questions asking about the symptoms are effective in identifying people who have been exposed to CO. In addition, the study will investigate whether people who have been exposed to CO are more likely to be diagnosed with dementia than people who haven't been exposed to CO.

Who can participate?

Adults who come to the Emergency Department with symptoms that are associated with known exposure to carbon monoxide (pain that appears to be from the heart, headache that is not from a head injury, flu-like symptoms, fits, fainting or feeling faint).

What does the study involve?

Patients who agree to participate will be assessed as usual in the A&E department. Participants will have blood taken within 30 minutes of the decision that they are eligible to participate and they will also be asked questions about their symptoms. If the patient's blood CO level is raised or the patient's answers to the CO screening questions indicate they may have been exposed to CO, a registered gas engineer will be alerted, with patient consent, to investigate the scene of the suspected exposure. The blood samples taken will undergo laboratory testing to investigate whether a test can be developed to detect CO that is more accurate than those currently available.

What are the possible benefits and risks of participating?

There is a benefit to the patient in the increased awareness of CO exposure that the study will bring as a potential cause for their symptoms. Patients will also receive an assessment by trained gas safety staff of any potential source of CO exposure within their home that could be harming them or the people they live with. There is a small risk that blood testing needs to be repeated due to the test not being successful. This is the same risk as for hospital blood taking and not as a consequence of the study.

Where is the study run from?

The Emergency Department Clinical Research Unit at St George's Hospital (UK)

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

November 2018 to April 2020

Who is funding the study?

The Gas Safety Trust (UK)

Who is the main contact?

Prof. Heather Jarman

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

39494

Study information

Scientific Title

The ED-CO study: a prospective enhance surveillance study of carboxyhaemoglobin levels in patients attending the Emergency Department with symptoms suggestive of carbon monoxide exposure

Acronym

ED-CO

Study objectives

The incidence of carbon monoxide (CO) exposure in England is not known; it is thought to be misdiagnosed by health professionals, with potential risks to patients of ill health and death. The primary aim of the project is to identify how commonly people presenting to emergency departments are actually exposed to CO, which will inform how policy makers and public health staff develop appropriate preventative strategies in future. The secondary aims are to evaluate a screening tool for CO exposure, to help to interpret levels of CO in patients' blood and to try to identify blood markers of CO exposure that are more reliable and easy to interpret than current tests. Lastly, recent evidence has suggested that there may be an association between dementia and CO exposure; hospital discharge codes will be scrutinised to estimate the frequency of a diagnosis of dementia and the different rates of dementia observed between patients who have and have not been exposed to carbon monoxide.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/10/2018, London - Queen Square Research Ethics Committee (HRA NRES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester M1 3DZ; nrescommittee.london-queensquare@nhs.net), ref: 18/LO/1381

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Carbon monoxide poisoning

Interventions

Patients presenting to the Emergency Department will have blood taken for analysis, have baseline information recorded about their symptoms, and be screened using a questionnaire for carbon monoxide (CO) exposure risk. If the patient has a raised carbon monoxide level detected in their blood or they are screened as potentially being exposed to CO a gas engineer will be alerted, with patient consent, to investigate the scene of a suspected exposure. This is the end of the patient's involvement in the study. Further detailed analysis of the blood samples will be undertaken to ascertain if a novel biomarker can be found that more readily detects CO in the blood than current methods.

Intervention Type

Mixed

Primary outcome(s)

Carboxyhemoglobin (COHb) level in blood sample provided on day of presentation to Emergency Department

Key secondary outcome(s)

1. Answers to questions in the COMA screening questionnaire provided by patient on day of presentation to Emergency Department
2. Time of year of confirmed or suspected CO exposure (summer versus winter) assessed using patient medical records and gas engineer data following presentation
3. Diagnosis of dementia during the 28 days following presentation assessed using patient medical records

Completion date

30/04/2020

Eligibility

Key inclusion criteria

1. Aged 18 years or older
2. Presenting to the ED with symptoms suggestive of cardiac chest pain, non-traumatic headache, flu-like symptoms unless suggestive of specific focus of infection, seizures or syncope /presyncope

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

4404

Key exclusion criteria

1. Aged under 18 years
2. Chest pain associated with chest wall tenderness or non-cardiac cause (pulmonary embolism, pneumothorax)
3. Recurrent situational syncope
4. Head injury
5. Actual or suspected smoke inhalation
6. Unable to understand the informed consent process and/or has a poor understanding of English (e.g. English-speaking relative/translator not available within timescales for study procedures)
7. Patients previously enrolled in this study

Date of first enrolment

07/12/2018

Date of final enrolment

30/03/2020

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

St George's Hospital

Blackshaw Road

London

United Kingdom

SW17 0QT

Study participating centre
Frimley Park Hospital
Portsmouth Road
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Wexham Park Hospital
Wexham Park Hospital
Slough
United Kingdom
SL2 4HL

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
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SM5 1AA

Sponsor information

Organisation
St George's University Hospitals NHS Foundation Trust

ROR
<https://ror.org/039zedc16>

Funder(s)

Funder type
Charity

Funder Name
Gas Safety Trust

Alternative Name(s)
GST

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2023	03/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.1	12/09/2018	16/08/2022	No	No