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

Submission date
13/05/2019

Recruitment status
No longer recruiting

Registration date
25/11/2019

Overall study status
Completed

Last Edited
03/01/2024

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/11/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 5222; UK Sample Size: 5222

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
England

United Kingdom

Study participating centre
St George's Hospital
Blackshaw Road
London
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SW17 0QT

Study participating centre
Frimley Park Hospital
Portsmouth Road
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GU16 7UJ

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

Study participating centre
St Helier Hospital
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SM5 1AA

Sponsor information

Organisation
St George's University Hospitals NHS Foundation Trust

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researchgovernance@sgul.ac.uk

Sponsor type
Hospital/treatment centre

Website
https://www.stgeorges.nhs.uk/education-and-research/research/

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

Publication and dissemination plan
The results of this study will be published in a high-impact factor peer-reviewed journal and will be presented at international conferences.

Intention to publish date
01/08/2021

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?
Protocol file	version 1.1	12/09/2018	16/08/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		01/09/2023	03/01/2024	Yes	No