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Non-invasive CPAP-Ventilation versus Oxygen-therapy using a simple face mask for Carbon Monoxide poisoning

Submission date
12/06/2014

Recruitment status
No longer recruiting

Registration date
20/06/2014

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims:
Carbon monoxide (CO) is a leading cause of poisoning. There are 40,000 to 50,000 reported cases in the United States per year. It is assumed, however, that many more cases go unreported as it is difficult to diagnose. This is due to the nonspecific symptoms (for example, nausea, feeling tired and confused, vomiting, stomach pains and difficulty breathing) than can be similar to food poisoning or flu. CO poisoning not only leads to a number of acute symptoms but also to chronic complaints weeks or even months after the actual poisoning has taken place, the so called "neuropsychiatric sequelae". These symptoms can include headaches, nausea, lethargy, confusion, emotional lability, amnesia, and even psychosis. Current standard treatment of CO poisoning consists of inhaling oxygen via a simple face mask. The aim of this study is to test whether supporting the patients own breathing using a tight face mask and a ventilation machine (respirator) reduces the occurrence of those "neuropsychiatric sequelae".

Who can participate?
Patients treated for acute CO poisoning can be included in the study if the level of CO measured in their blood ("COHb") was at least 7% and they are at least 18 years old, not pregnant and that there was no need to insert a special tube to facilitate ventilation into their trachea ("intubation")

What does this study involve?
Patients are randomly assigned to either standard therapy (oxygen inhalation via a simple face mask) or study therapy (tight face mask and ventilation machine). During therapy CO-levels are continuously measured. Therapy will be stopped when CO-levels reach 3% or below. After completion of the therapy, a neuropsychiatric test will be performed. Patients will be contacted one month later to perform the test again, and will be asked about their quality of life.

What are the possible benefits and risks of participating?
All participants receive close monitoring and follow-up of their symptoms and quality of life.
If the study hypothesis proves to be true, patients in the intervention group (those that were treated with study therapy) receive a better treatment with the potential to reduce later

complaints.
There are no anticipated risks from participation, however the face mask may feel uncomfortable for some patients.

Where is the study run from?
The study is run by the Department of Emergency Medicine of the Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
June 2014 to July 2015

Who is funding the study?
Austrian Association of Emergency and Disaster Medicine (Austria)

Who is the main contact?
Dr. Dominik Roth
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Non-invasive CPAP-ventilation versus oxygen-therapy using a simple face mask for carbon monoxide poisoning: A single-center, randomised assessor-blinded controlled parallel-group study

Acronym
CO-CPAP

Study objectives
Non-invasive CPAP ventilation using a tight face mask reduces the incidence of neuropsychological sequelae 1 month after carbon monoxide intoxication compared to standard oxygen inhalation using a simple face mask with oxygen reservoir.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical University of Vienna Ethics Committee, 19/05/2011, ref. 251/2011

Study design
Single-center, randomised assessor-blinded controlled parallel-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Carbon monoxide poisoning

Interventions
Intervention: Non-invasive CPAP ventilation using a tight mask and standard respirator equipment
Control: Oxygen inhalation therapy by a simple facemask with oxygen reservoir

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Absence of neuropsychological sequelae 1 month after intoxication

Secondary outcome measures
1. Time until COHb-level reaches 3% or less
2. Changes in neuropsychological sequelae between hospital discharge and 1 month after intoxication
3. Quality of life after 1 month
4. Mortality after 1 month
5. Adverse events
6. Length of Stay at ICU
7. Length of stay in hospital
8. Hospital admission within 1 month

Overall study start date
25/06/2014

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Adult patients (i.e. at least 18 years old) treated at the Emergency Department
2. Elevated levels of COHb (COHb >= 7%) AND either assured CO-exposition (for example, faulty gas-heater, fire) or symptoms consistent with CO poisoning

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
74

Key exclusion criteria
1. Patients being comatose on admission
2. Patients intubated by Emergency Medical Service
3. Patients requiring mechanical ventilation
4. Pregnant women

Date of first enrolment
25/06/2014

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
Austria

Study participating centre
Department of Emergency Medicine
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

Sponsor details
c/o Assoc. Prof. Dr. Christof Havel
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Sponsor type
University/education

Website
http://www.meduniwien.ac.at/homepage/1/homepage/

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Research organisation

Funder Name
Austrian Association of Emergency and Disaster Medicine: Reinhard Malzer scientific fund (Austria)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration