The use of helium after resuscitation: a safety and feasibility study

Published: 02-03-2010
Last updated: 04-05-2024

The objective of this trial is to investigate the feasibility and safety of helium ventilation post cardiac arrest.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32848

Source
ToetsingOnline

Brief title
HERES

Condition

- Other condition
- Coronary artery disorders
- Central nervous system vascular disorders

Synonym
Cardiac arrest, Resuscitation

Health condition

Status na reanimatie ivm circulatiestilstand

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac arrest, Helium, Organ protection, Resuscitation

Outcome measures

Primary outcome

The main endpoint will be the occurrence of adverse events due to helium ventilation. This is defined as death or the necessity to stop ventilation using helium. The safety committee of this study will judge whether the adverse events occurred due to helium ventilation or had another cause..

Secondary outcome

Neurological: biomarkers for cerebral damage (neuron specific enolase levels 24 and 48 hours after admission), neurological outcome 30 after admission, as measured using the Glasgow outcome scale.

Cardiological: biomarkers of myocardial damage (troponine-T, CK, CK-MB) assessment cardiac injury by echocardiography (in the first 72 hours after admission and at day 30).

Pulmonary: Bloodgasanalysis, veneus saturation and settings of the ventilator during the first 6 hours.

Study description

Background summary

Even after a successful resuscitation after cardiac arrest, 50% of the patients

admitted to the ICU die. Since most patients die due to brain damage sustained during the ischemia and reperfusion during the event and subsequent restoration of the circulation, neuroprotective strategies are needed. In animal experiments, helium inhalation during reperfusion has been shown to reduce the size of cerebral infarction. Since helium has no known side effects, this might be an attractive strategy for reducing neurological damage. We hypothesize that helium ventilation post-resuscitation is both safe and feasible.

Study objective

The objective of this trial is to investigate the feasibility and safety of helium ventilation post cardiac arrest.

Study design

A single centre open-label intervention trial.

Intervention

Participants will be ventilated using a helium-oxygen gas mixture, with a FiO2 of 40-50%, during the first 3 hours after inclusion in the study.

Study burden and risks

The safety and feasibility of ventilating patients after CPR can only be investigated in this group. We expect that no adverse events due to helium ventilation will occur, all assessments needed for this study are part of standard patient care. A participating patient will not benefit directly from this treatment, but potentially helium ventilation may have a neuro- and cardioprotective effect. If helium ventilation turns out to be safe and feasible, a larges study investigating effectiveness will be conducted in patients after CPR

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Admission to the ICU after successful resuscitation after witnessed out-of-hospital cardiac arrest
- Post-anoxic coma on admission
- First registered rhythm ventricular fibrillation (VF) or ventricular tachycardia (VT)
- Return of spontaneous circulation within 30 minutes of arrest
- Ability to start study medication within 6 hours after arrest
- Treatment with induced mild hypothermia

Exclusion criteria

- No informed consent
- Co-morbidity with a life expectancy of <6 months prior to cardiac arrest
- Pregnancy
- Neurological disorder prior to cardiac arrest
- Severely disabled prior to arrest
- A pulmonary condition requiring ventilation with a FiO2 >50% and > 10 cm H2O PEEP at the time of inclusion.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Heliox
Generic name:	Helium
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	16-03-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-017499-26-NL
CCMO	NL30466.018.09