The use of helium after cardiac arrest.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20392

Source
NTR

Brief title
HERES study

Health condition

Cardiac arrest (hartstilstand)
Resuscitation (reanimatie)
Postanoxic coma (postanoxisch coma)
Helium (helium)

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, University of Amsterdam

Intervention

Outcome measures

Primary outcome

Occurence of major adverse events (death, inability to effectivly ventilate using helium/oxygen).

Secondary outcome

1. Arterial blood gas;

2. Ventilator settings;

3. Creatine Kinase;

4. Creatine Kinase MB;

5. Troponin-T;

6. Neuro Specific Enolase;

7. Glassgow Outcome Score;

8. Mortality;

9. Duration of mechanical ventilation;

10. Length of stay on ICU.

Study description

Background summary

N/A

Study objective

Helium can be safely used in patients admitted to the ICU after resuscitation for out-of-hospital cardiac arrest.

Study design

1. ABG at 0, 1, 2, 3, 4, 5 and 6 hours;

2. Ventilator settings at 0, 1, 2, 3, 4, 5 and 6 hours;

3. CK at 0, 6, 12, 18, 24 and 48 hours;

4. CK-MB at 0, 6, 12, 18, 24 and 48 hours;

5. Troponin-T at 0, 6, 12, 18, 24 and 48 hours;

6. NSE at 24 and 48 hours;

7. Glassgow Outcome Score at 30 days;

8. Mortality at 30 days.

Intervention

Ventilation with helium/oxygen (50%/50%) during the first 3 hours after inclusion.

Contacts

Public
Postbus 22660, M0-126
Daniel Brevoord
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111
Scientific
Postbus 22660, M0-126
Daniel Brevoord
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Eligibility criteria

Inclusion criteria

1. Admission to the ICU with postanoxic coma after OHCA;

2. First registered rhythm VF/VT;

3. Witnessed arrest;

4. Return of spontaneous circulation within 30 minutes;

5. Induced mild hypothermia;

6. Ability to start study medication within 6 hours.

Exclusion criteria

1. Life expectancy < 6 months prior to arrest;

2. Neurological disosrder prior to arrest;

3. Severly disabled prior to arrest;

4. Pregnancy;

5. Pulmonary illness, requiring ventilation with >50% FiO2 and > 10 cmH2O PEEP.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2010
Enrollment:	25
Type:	Actual

Ethics review

Positive opinion

Date:	24-03-2010
Application type:	First submission

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
NTR-new	NL2133
NTR-old	NTR2257
Other	METC AMC / CCMO : MEC 09/333 / NL 30466.018.09 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A