Helium in Ischemic Stroke.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25537

Source
Nationaal Trial Register

Brief title
HIS

Health condition

Helium, ischemic stroke.
helium, ischemische beroerte.

Sponsors and support

Primary sponsor: Tergooiziekenhuizen
Rijksstraatweg 1, 1261 AN Blaricum,
The Netherlands.
Phone: +31 35 539 11 11
Source(s) of monetary or material Support: Tergooiziekenhuizen
Rijksstraatweg 1, 1261 AN Blaricum,
The Netherlands.
Phone: +31 35 539 11 11

Intervention

Outcome measures

Primary outcome

1. Main safety endpoint: Clinical deterioration, defined as a decrease on the Glasgow Coma Scale of more than 2 points and/or a decrease of 4 or more points on the NIHSS;

2. Primary clinical endpoint: Comparison of the change in neurological deficits, quantified by the National Institute of Health Stroke Scale (NIHSS) during helium therapy.

Secondary outcome

1. Safety endpoint: Death by any cause and total and specific serious adverse events, including symptomatic heamorrhagic transformation or intracrananial heamorrhage;

2. Secondary clinical endpoints: Neurological deficits at 4 hours, 24 hours, 1 week and at 3 months, quantified on NIHSS and the level of dependency measures on the modified Rankin Scale (mRS) at three months.

Study description

Background summary

In the treatment of acute cerebral ischemia the aim is to preserve and salvage the penumbra and to protect the brain from reperfusion injury. Recently, helium was shown to provide neuroprotection in an experimental setting of cerebral ischemia-reperfusion. Substantial evidence of organ protection by noble gases exists in the field of cardioprotection. In the absence of evidence of neuroprotection by helium in human, further investigation is necessary. Our aim is to investigate the safety and feasibility of helium administration in patients with acute ischemic stroke, not eligible for trombolysis.

Study objective

Primary objective: Is 4 hours of inhalation of a gaseous mixture of 79% helium and 21% oxygen feasible and save in acute ischemic stroke?

Study design

T0: Start of helium breathing for 4 hours;

T1= 4 hours: Clinical evaluation using the NIHSS and VAS-sccore;

T2= 24hours: Clinical evaluation using NIHSS;

T3= 1 week: Clinical evluation using NIHSS;

T4= 3 months: Clinical evaluation using NIHSS and mRS.

Intervention

Helium breathing trough a mask during 4 hours in the intervention group compared to normal air in control group.

Contacts

Public
Rijksstraatweg 1
J.R. Kruijk, de
Blaricum 1261 AN
The Netherlands
+31 (0)35 5391111
Scientific
Rijksstraatweg 1
J.R. Kruijk, de
Blaricum 1261 AN
The Netherlands
+31 (0)35 5391111

Eligibility criteria

Inclusion criteria

1. Age >=18 years, not eligible for rt-PA;

2. Clinical anterior circulation ischemic stroke diagnosed by an independent physisian;

3. < 12 hours of witnessed symptom onset;

4. NIHSS >=4;

5. Pre-admission mRS <=1;

6. Visual estimation of penumbra/infarct ratio > 20% on Ct-perfusion;

7. Informed consent.

Exclusion criteria

1. Eligible for rt-PA thrombolysis;

2. Inability to obtain written informed consent;

3. Legal incapacity;

4. Medically unstable (blood pressure > 230/120 or <100/60mmHg, pulse > 120 bpm, body temperature > 39C);

5. Intracerebral haemorrhage on admission non-enhanced CT;

6. Rapidly improving neurological deficits;

7. Pregnancy;

8. Impaired renal function (serum creatinin levels > 130micromol/L);

9. Allergic to contrast agent;

10. Use of anticoagulation drugs or coagulopathy (PTT > 1.5 times control);

11. Use of following nephrotoxic mediactions: aminoglycosids, amfoterine B or cisplatin;

12. Contra-indication or intolerance to any substance;

13. Saturation on admission of < 90%.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-02-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33571
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2114
NTR-old	NTR2231
CCMO	NL21743.003.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33571

Study results

Summary results
N/A