Reduction of brain damage after perinatal arterial stroke (PAS) with recombinant human erythropoietine (rhEPO): "feasibility" and "safety study".

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To investigate if rhEPO has a positive effect on MRI/MRA parameters compared to infants with stroke without rhEPO collected from historical data.To investigate if rhEPO (3 dosages of 1000IU/kg/day) for perinatal stroke has no negative side-effects...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON33752

Source
ToetsingOnline

Brief title
reduction of braindamage after rhEPO

Condition

- Congenital and peripartum neurological conditions

Synonym
cerebral arterial infarction, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain, Neonate, rhEPO, Stroke

Outcome measures

Primary outcome

Positive effects on MRI/MRA parameters (size of stroke, less Wallerian

degeneration) compared to historical data.

Secondary outcome

Side effects of EPO.

Study description

Background summary

Cereral arterial stroke in the perinatal period has an incidence of 1/3000-4000 in newborns. PAS causes abnormal cognitive and neuromotor development and outcome in 30-57%. This complication is therefore an important 'target' for therapy for reduction of reduction of braindamage. Recently a study described adults treated for stroke with rhEPO 900IU/kg, without side-effects, had a significant better outcome compared to placebo-treated group, without side effects of rhEPO.
The neuroprotective activity of rhEPO (neurotroph, angiogenesis, anti-inflammatory, anti-apoptic activity) was already shown in animal experimental research. It showed that rhEPO is effective in case of global hypoxic-ischemia as well as focal cerebral ischemia of the middle cerebral artery with a reduction of the size of the stroke up to 40%. Furthermore, rhEPO has been clinically used for anemia in preterm born infants, with a dosages until 700 IU/kg and even higher during a prolonged period of time (4 - 8 wks) without side effects.

Study objective

To investigate if rhEPO has a positive effect on MRI/MRA parameters compared to infants with stroke without rhEPO collected from historical data.
To investigate if rhEPO (3 dosages of 1000IU/kg/day) for perinatal stroke has no negative side-effects on red bloodcell count or clotting system,

bloodpressure, edema.

Study design

All newborn infants with a gestational age of 36 wks admitted to our Neonatal Intesive Care Unit with the diagnosis perinatal arterial stroke (PAS) diagnosed with cerebral ultrasound or MRI/MRA. Chormosomal/congenital abnormalities are exclusion criteria.
Immediately after the diagnosis and parental consent rhEPO (1000IU/kg, iv) will be given, repeated after 24 h and 48h. Historical data will be used for comparison.
MRI/MRA will be performed to confirm the diagnosis, this will be repeated after 1 week and after 3 months. This is routine clinical care.

Intervention

Immediately after the diagnosis and parental consent rhEPO (1000IU/kg, iv) will be given, repeated after 24 h and 48h. Historical data will used as a control group.

Study burden and risks

MRI/MRA is routine clinical care in patients with PAS.
Extra bloodsample during routine clinical blood withdrawals, for isoprostane, Non-protein bound iron.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Perinatal arterial infarction (PAS) in the brain.

Exclusion criteria

Congenital and/or chromosomal problems.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2009

Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NeoRecormon 2000
Generic name:	Epoetine Beta
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	09-06-2009
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	02-06-2010
Application type:	First submission
Review commission:	METC NedMec

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	EUCTR2007-002078-71-NL

Register	ID
CCMO	NL16758.041.07