2-STEP: A single-centre, phase II study to evaluate the safety, tolerability and pharmacokinetics of 2-Iminobiotin (2-IB) in neonates with gestational age of *36 weeks with moderate to severe perinatal asphyxia treated with therapeutic hypothermia

Published: 19-01-2015
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To explore the safety, tolerability and the pharmacokinetic profile of 2-IB when given on top of therapeutic hypothermia.

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

Summary

ID

NL-OMON43724

Source
ToetsingOnline

Brief title
2-STEP

Condition

- Congenital and peripartum neurological conditions

Synonym
neonatal asphyxia; oxygen shortage at birth

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Neurophyxia BV,Subsidie van de producent van 2-Iminobiotin

Intervention

Keyword: 2-Iminobiotin, perinatal asphyxia, Pharmacokinetics, Safety

Outcome measures

Primary outcome

To explore the safety, tolerability and the pharmacokinetic profile of 2-IB

when given on top of therapeutic hypothermia.

Secondary outcome

- To gather preliminary signs of short term efficacy as defined by the Lac/NAA

ratios using MRS at 3-7 days after birth and the percentage of surviving

patients with a normal aEEG at 60h after birth.

Study description

Background summary

Perinatal asphyxia is a rare but life-threatening condition. The introduction of therapeutic hypothermia as standard care has improved the outcome of these patients, but still almost half of the treated neonates die or have serious long term morbidity. For that reason additional neuroprotective treatment is warranted. 2-IB has shown to be effective in multiple animal models in substantially diminishing the neurological damage after perinatal asphyxia. Also it has shown to be safe and well tolerated in both juvenile and adult animal models, in adult human volunteers and in a small group of neonates suffering from perinatal asphyxia but not treated with hypothermia.

Study objective

To explore the safety, tolerability and the pharmacokinetic profile of 2-IB when given on top of therapeutic hypothermia.

Study design

Open label phase II study

Intervention

None, all subjects are treated with 2-Iminobiotin in addition to standard care

Study burden and risks

The additional burden placed on subjects in this trial is minimal and does not interfere with standard care. The risks associated with administration of 2-Iminobiotin are judged to be minimal since no relevant adverse reaction were reported to date. Based on the vulnerable population, the overall risk classification is upgraded to *moderate* with a subsequent monitoring plan. On an individual level, administration of 2-Iminobiotin could have a positive therapeutic effect. On a group level, information will become available regarding pharmacokinetics and safety, which is of great importance for further clinical research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Neonates with * 36 and <44 weeks gestation who are eligible to receive therapeutic hypothermia.
2. Ability to start treatment within 12 hours after birth.

Exclusion criteria

1. Inability to insert an indwelling catheter (umbilical venous catheter or percutaneously inserted central catheter, preferably multiple lumen) for administration of the drug or an arterial line for recurrent blood sampling.
2. Major congenital malformations, specifically malformations that may affect the renal function.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	07-09-2015
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	2-Iminobiotin

Ethics review

Approved WMO Date:	19-01-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-04-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-06-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2014-004265-25-NL
CCMO	NL50996.041.14