Levetiracetam (Keppra®) in neonates

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Objective: Primary objective: safety profile of LEV in neonates. Safety outcome parameters as liver, kidney and metabolic function, electrolytes, hemodynamic effects (heart rate/arrhythmia, arterial blood pressure/hypotension). Investigation of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON30449

Source
ToetsingOnline

Brief title
-

Condition

- Seizures (incl subtypes)

Synonym
convulsions, epileptic seizures

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: UCB Pharma

Intervention

Keyword: anti-epileptic drug, neonatal seizures, safety

Outcome measures

Primary outcome

Safety profile of LEV in neonates. Outcome parameters as liver-, kidney- and metabolic function, electrolytes, hemodynamic effects (heart rate/arrythmias, arterial bloodpressure/hypotension). Investigation of pharmacokinetic and -dynamic properties of LEV at neonates.

Secondary outcome

Increase of epileptic seizures and medication interaction will be measured.

Study description

Background summary

Background: Both clinical and laboratory studies demonstrate that neonatal seizures can cause cognitive, behavioural or epileptic complications later in life. Therefore, treatment is needed. On the other hand, commonly used anticonvulsants can have a harmful effect on the developing brain. A mild safety profile, a different antiseizure mechanism and indications for neuroprotective properties make levetiracetam (LEV) (Keppra®) interesting for the use in neonates.
Hypothesis: The use of parenterally administered LEV in neonatal epileptic seizures, detected electrographically, with or without clinical signs, will be safe.

Study objective

Objective: Primary objective: safety profile of LEV in neonates. Safety outcome parameters as liver, kidney and metabolic function, electrolytes, hemodynamic effects (heart rate/arrhythmia, arterial blood pressure/hypotension). Investigation of pharmacokinetic and -dynamic properties of LEV in neonates.
Secondary objective: Increase of epileptic activity and drug interaction will be determined or registered.

Study design

Open label pilot study.

Intervention

Levetiracetam intravenously as a second or third line anticonvulsant, 20 mg/kg; in the absence of a response after 10 min. a second dose of 20 mg/kg will be given.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As all patients with (increased risk for) neonatal seizures EEG electrodes will be applied. All patients admitted to the NICU will receive an arterial catheter. Blood samples will be taken from the arterial catheter. Fifteen samples of 0.3 ml in the first 72 hours after inclusion will be drawn for LEV plasma concentrations. Three samples of 0.5 ml will be drawn for liver- and kidney functions and electrolytes.
Known side-effects in children and adults are dizziness, somnolence, fatigue, behavioral disturbances. There are no effects on respiratory or kidney function. An increase in heart rate and arterial blood pressure was seen in dogs after a dose 10-fold the human used dose. In human studies no cardiovascular side-effects were seen. In conclusion, this safety study is needed to determine the possible side-effects in neonates, but in older patients the side-effects are minimal, and the burden regarding the procedures is minimal.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

·newborn gestational age >= 37 weeks, birth weight > 1500 grams
·refractory to phenobarbitone up to 40 mg/kg or refractory to phenobarbitone up to 40 mg/kg and midazolam up to 0.5 mg/kg (raised from 0.1 mg/kg every 10-15 minutes when effect fails)
·after correction or treatment of metabolic causes as inborn errors, hypoglycemia or hypocalcaemia or CNS infections

Exclusion criteria

·newborn gestational age < 37 weeks, birth weight < 1500 grams

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):	12-05-2007

Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Keppra
Generic name:	Levetiracetam
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	22-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2006-006804-12-NL
CCMO	NL15182.078.06