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Levetiracetam (Keppra®) in neonates: safety of intravenous levetiracetam for neonates with seizures

Submission date	Recruitment status	[ ] Prospectively registered
11/04/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/04/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/09/2021	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL907 (NTR930)

Study information

Scientific Title

Levetiracetam (Keppra®) in neonates: safety of intravenous levetiracetam for neonates with seizures

Study objectives
The use of parenterally administered Levetiracetam (LEV) (Keppra®) in neonatal epileptic seizures, detected electrographically, with or without clinical signs, will be safe, and pharmaco-kinetic and -dynamic properties of the use in neonates will be determined.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the METC Erasmus MC Rotterdam on the 12th March 2007.

Study design
Non-randomised, non-controlled, clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neonatal seizures

Interventions
Keppra® intravenous (iv) 20 mg/kg, when no response another 20 mg/kg. 15 times withdrawal from blood from arterial catheter.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Levetiracetam (Keppra®)

Primary outcome(s)
1. Safety profile of LEV in neonates
2. Safety outcome parameters as liver, kidney and metabolic function, electrolytes, haemodynamic effects (heart rate/arrhythmia, arterial blood pressure/hypotension)
3. Investigation of pharmaco-kinetic and -dynamic properties of LEV in neonates

At t = 0, 12 and 24 hours physical examination will be performed. Vital signs and EEG will be monitored continuously up to 24 hours. Hepatic and kidney functions will be determined at t = 0 and t = 24 hours. LEV plasma concentrations at t = 0, 5, 15, 20, 30, 60 minutes and t = 4, 8, 12, 24, 36, 48, 60 and 72 hours.

Key secondary outcome(s))

Increase of epileptic activity and drug interaction will be determined or registered.

At t = 0, 12 and 24 hours physical examination will be performed. Vital signs and EEG will be monitored continuously up to 24 hours. Hepatic and kidney functions will be determined at t = 0 and t = 24 hours. LEV plasma concentrations at t = 0, 5, 15, 20, 30, 60 minutes and t = 4, 8, 12, 24, 36, 48, 60 and 72 hours.

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. All neonates with electrographical epileptic seizures, diagnosed by Electroencephalogram (EEG):
a. with or without clinical signs
b. multiple (greater than one in 30), defined as the evolution of sudden, repetitive evolving stereotyped forms with a definite beginning, middle and end, lasting at least eight seconds
c. or status epilepticus, defined as continuous seizure activity for at least 30 minutes or recurrent seizure activity for greater than 50% of the entire recording duration
2. Newborn gestational age greater than 37 weeks, birth weight greater than 1500 grams
3. 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 to 15 minutes when effect fails) (depending on moment of referral with history of medication)
4. After correction or treatment of metabolic causes of the as inborn errors, hypoglycaemia or hypocalcaemia or Central Nervous System (CNS) infections
5. Arterial catheter

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
Not Specified

Key exclusion criteria
1. Newborn gestational age less than 37 weeks
2. Birth weight less than 1500 grams

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration