Pharmacokinetics of Lorazepam Oral Liquid in Paediatric ICU Patients

No registrations found.

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

Summary

ID

NL-OMON24356

Source
NTR

Brief title
PK of Lorazepam Oral Liquid in PICU Patients

Health condition

PICU, sedation, weaning, withdrawal, IC kinderen, ontwenning, sedatie, afbouwen, oraal

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

PK parameters

Secondary outcome

influence of co-variates

Study description

Study design

48 hrs

Intervention

I.V. and oral administration of lorazepam

Contacts

Public
L. Hanff
Hospital Pharmacy Erasmus MC
Dr. Molewaterplein 60
Rotterdam 3015 GJ
The Netherlands
Scientific
L. Hanff
Hospital Pharmacy Erasmus MC
Dr. Molewaterplein 60
Rotterdam 3015 GJ
The Netherlands

Eligibility criteria

Inclusion criteria

age between 2 weeks and 12 years,

signed consent from the parent or legal assent,

admitted to the paediatric ICU,

indwelling intravenous or arterial catheter,

scheduled to start the weaning protocol with oral lorazepam.

Exclusion criteria

concomitant treatment with another investigational drug,

contraindications for lorazepam use;

Severe liver insufficiency, defined as 5 times upper level of ALAT and ASAT

Hypersensitivity to lorazepam,

Myasthenia gravis.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-03-2015
Application type:	First submission

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
NTR-new	NL4974
NTR-old	NTR5112
Other	LORA01 : 2015-001043-37

Study results