Pharmacokinetics of levetiracetam after rectal administration in healthy volunteers

Published: 17-12-2007
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Comparison of single-dose pharmacokinetics of levetiracetam after rectal versus oral administration at healthy volunteers.

Ethical review	Approved WMO
Status	Completed
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON30934

Source
ToetsingOnline

Brief title
PK levetiracetam rectal

Condition

- Neurological disorders NEC

Synonym
epilepsia

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Atrium Medisch Centrum Parkstad;afdeling klinische farmacie

Intervention

Keyword: levetiracetam, pharmacokinetics, rectal, volunteers

Outcome measures

Primary outcome

- Area-under- the-curve (AUC)

- Relative bioavailability (Frel= AUCrectal/AUCoral)

Secondary outcome

- Maximum concentation (Cmax)

- Time to maximum concentration (Tmax)

- Clearance (Cl)

- Volume of distribution (Vd)

- Elimination constant (Kel)

- Elimination half-life(T1/2)

Study description

Background summary

Less research has been done to the rectal administration of levetiracetam.
In only 2 case reports levetiracetam suspension was administered rectal.
From these dates becomes clear that levetiracetam is absorbed after rectal administration. However the steady-state concentrations were lower than after oral administration.

Study objective

Comparison of single-dose pharmacokinetics of levetiracetam after rectal versus oral administration at healthy volunteers.

Study design

Single-center, not-blinded, 2-period cross-over study with 12 healthy

volunteers.

Study burden and risks

Before participation the test persons have to fill in aquestionnaire en thet have to give blood and urine for screening (blood: creatinine, ASAT, ALAT, gammaGT, Hb en Ht; urine: protein, glucose, pH).
For the research itself, they should be in the hospital twice for a whole day and twice for just one blood sample.
During research there will be administered once a tablet Keppra and once a suppository levetiracetam.
Via a catheter blood will be taken on 14 fixed times (+/- 6 ml). The morning after one blood sample will be taken.
During research there will be asked for possible adverse effects. The expectation is that these will be minimal, because it's only one administration of a low dose levetiracetam.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy volunteers
18-55 years
conformed consent

Exclusion criteria

patients with epilepsia
pregnant women
breast feeding women
bad renal function
bad liver function

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-09-2008
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Keppra
Generic name:	levetiracetam
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	n.v.t.
Generic name:	levetiracetam

Ethics review

Approved WMO Date:	17-12-2007
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2007-003243-76-NL
CCMO	NL18256.096.07