Pharmacokinetics of haloperidol

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Search for a relation between the concentration of haloperidol in serum and in liquor in elderly who reached a steady state of haloperidol. Secundairy aim: Cal inter-individual variation in serum and CSF concentrations, at the same dose haloperidol...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON39461

Source
ToetsingOnline

Brief title
Pharmacokinetics of haloperidol

Condition

- Other condition
- Movement disorders (incl parkinsonism)

Synonym
pharmacokinetics

Health condition

farmacokinetiek van een geneesmiddel/antipsychoticum

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cerebrospinal fluid, Haloperidol, Pharmacokinetics

Outcome measures

Primary outcome

concentration haloperidol in serum and liquor

Farmacogenetic polymorfisms of the cytochroom P450 enzym CYP2D6

Secondary outcome

age, gender, race, smoking, medication use

Study description

Background summary

Haloperidol is the first choice antipsychotic drug for the treatment of delirium or behavioural problems in dementia. In elderly there is a large variability in effects and side-effects of haloperidol. There is no previous research which decribes the relation between plasma haloperidol concentration and liquor haloperidol concentration. Farmacogenetic variation in polymorfisms of the cytochroom P450 enzym CYP2D6 is a possible explanation for the inter individual variation in blood levels of haloperidol at the same dose.

Study objective

Search for a relation between the concentration of haloperidol in serum and in liquor in elderly who reached a steady state of haloperidol. Secundairy aim: Cal inter-individual variation in serum and CSF concentrations, at the same dose haloperidol, be explained by polymorfisms in CYP2D6 allels?

Study design

Cross sectional study design

Study burden and risks

The attending physician treats the patients with regular care. To take an extra tube cerebrospinal fluid with the spinal anaesthesia gives a slightly elevated

risk of post dural puncture headache.
The incidence of post dural puncture headache is 5-15%. It is caused by excessive loss of cerebrospinal fluid. When a patient sits or stands straight, the pressure in the head is lower what can cause a headache. Leakage of cerebrospinal fluid and the headache are not dangerous.
Taking a tube blood gives a risk of a hematoma.
No oral haloperidol on the morning of the surgery does not matter, because after five days of haloperidol a steady state is reached.

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

age >64 years
elective operation with spinal anesthesia

elevated risk to develop a delirium and prescription of haloperidol during five days pre-operative in a dose of 1mg/dag as regular care
mentally competent
informed consent

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	12-01-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-02-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	06-03-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL35631.028.11