Pharmacokinetics of haloperidol

Published: 11-01-2012 Last updated: 27-04-2024

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 reviewApproved WMOStatusRecruitment stoppedHealth condition typeOther 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 interindividual 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 preoperative 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