Pilot trial: Propofol in head-injured patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22558

Source
Nationaal Trial Register

Brief title
Propofol-CSF

Health condition

1. Propofol;

2. intracranial pressure;

3. sedation.

Sponsors and support

Primary sponsor: University Medical Center Groningen, Department of Neurology, the Netherlands
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Pharmacokinetic and pharmacodynamic parameters (BIS, ICP), intra- and interindividual variability and identification of covariates.

Secondary outcome

Correlation GCS and Bispectral index for further investigation to study the clinical usefulness of the Bispectral index in severe brain-injured patients.

Study description

Background summary

Background:

Little is known about the dose regimen of propofol in patients with increased intracranial pressure. Especially in neurological patients and long-term high-doses, knowledge of PK and PD of propofol is important, since propofol is associated with the propofol-infusion syndrome.

Method:

Propofol cerebrospinal fluid and whole blood samples will be determined simultaneously. The Bispectral analysis is recorded in addition to the GCS. Population PK and PD modelling will be performed with NONMEM.

Study objective

Because little is known on the effective and safe dosage of propofol when used for control of intracranial pressure in head-injured patients, propofol blood and cerebrospinal fluid concentrations and pharmacodynamics are characterized in order to optimize dose regimens.

The bispectral index (BIS) may be of additional value to assess the depth of sedation and the neurological outcome in head-injured intensive care patients.

Study design

N/A

Intervention

Observational study.

Contacts

Public
St Antonius Hospital
Department of Clinical Pharmacy
PO Box 2500
MYM Peeters
Nieuwegein 3430 EM
The Netherlands
0031306092612
Scientific
St Antonius Hospital
Department of Clinical Pharmacy
PO Box 2500
MYM Peeters
Nieuwegein 3430 EM
The Netherlands
0031306092612

Eligibility criteria

Inclusion criteria

1. Severe traumatic brain injury (GCS <=8);

2. indication propofol for sedation and control of increased intracranial pressure;

3. presence of intraventricular drain;

4. age >=18, men en women;

5. possibility to locate BIS sensors.

Exclusion criteria

1. Known allergy for propofol or egg-lecithin;

2. pregnancy or lactation;

3. use of remifentanil.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2006
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	09-03-2006
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	NL622
NTR-old	NTR681
Other	:
ISRCTN	Incomplete info for ISRCTN

Study results

Summary results
N/A