

# Pilot trial: Propofol in head-injured patients.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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

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## Eligibility criteria

### **Inclusion criteria**

1. Severe traumatic brain injury (GCS  $\leq 8$ );
2. indication propofol for sedation and control of increased intracranial pressure;
3. presence of intraventricular drain;
4. age  $\geq 18$ , 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:	Non controlled trial
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