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# The pharmacokinetics of nimodipine, intravenous and orally, in patients with subarachnoidal haemorrhage admitted in intensive care

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| **Submission date**<br>08/02/2007 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>08/02/2007 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>04/03/2008 | **Condition category**<br>Circulatory System | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N/A

# Study information

### Scientific Title

### Study objectives
Describing the pharmacokinetics of nimodipine, especially the variability of the bio-availability of orally administred nimodipine.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the local medical ethics committee

### Study design
Interventional, non-randomised, pharmacokinetic study

### Primary study design
Interventional

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Subarachnoidal haemorrhage

### Interventions
Blood samples according to strict time protocol during treatment.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Nimodipine

### Primary outcome measure
1. Pharmacokinetics of nimodipine in this specific group of patients
2. Variability of bio-availability of orally administred nimodipine

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
01/12/2006

### Completion date
01/12/2007

## Eligibility

### Key inclusion criteria
1. All patients admitted to the Intensive Care Unit (ICU) with subarachnoidal bleeding /haemorrhage (SAB), treated according to our SAB-protocol
2. Adults aged 18 to 70 years old

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
12

### Key exclusion criteria
1. Pregnancy
2. Expected mortality in less than 24 hours
3. Severe hepatic function disorders
4. Use of medication with known interaction in relation to nimodipine

### Date of first enrolment
01/12/2006

### Date of final enrolment
01/12/2007

## Locations

### Countries of recruitment

Netherlands

**Study participating centre**
**VU University Medical Centre**
Amsterdam
Netherlands
1081 HV

# Sponsor information

**Organisation**
VU University Medical Centre (VUMC) (The Netherlands)

**Sponsor details**
Department of Intensive Care
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.vumc.nl/english/

**ROR**
https://ror.org/00q6h8f30

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
VU University Medical Centre (VUMC) (The Netherlands)

# Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration