ISRCTN45381163 https://doi.org/10.1186/ISRCTN45381163

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr B M Kors

Contact details
VU University Medical Centre
Afdeling intensive care volwassenen
Boelelaan 1117
Amsterdam
Netherlands
1081 HV
+ 31 (0)20 444 3900
bm.kors@vumc.nl

Additional identifiers

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

Primary study design
Interventional

Study design
Interventional, non-randomised, pharmacokinetic study

Study type(s)
Treatment

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(s)
1. Pharmacokinetics of nimodipine in this specific group of patients
2. Variability of bio-availability of orally administred nimodipine

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration