

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/03/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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 administered 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 administered 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