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Influence of intravenous versus oral administration, arterial versus venous sampling and gender on pharmacokinetic-pharmacodynamic modelling of morphine and morphine-6-glucuronide-induced pain relief in healthy volunteers

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/05/2009	Other	[ ] 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

Protocol serial number
NTR229

Study information

Scientific Title

Study objectives
This study is designed to get a full pharmacokinetic-pharmacodynamic (PK/PD) characteristic of the opioid analgesic morphine and its active metabolite M6G after oral and intravenous (iv) infusion and to test whether sex differences exist in the analgesic behaviour of both opioids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Primary study design
Interventional

Study design
Randomised double blind active controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-operative pain

Interventions
Drug administration (blinded): morphine or M6G.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine

Primary outcome(s)
Pain relief related parameters (Visual Analogue Scale [VAS] to heat pain) in males versus females.

Key secondary outcome(s)
PK parameters

Completion date
01/11/2006

Eligibility

Key inclusion criteria
Healthy volunteers, aged 18+ years

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Body mass index (BMI) greater than 30 kg/m^2
2. Pregnancy or lactation
3. Presence of medical disease
4. Presence of psychiatric disease
5. Allergy to study medication
6. History of drugs or alcohol abuse

Date of first enrolment
01/11/2005

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
CeNes Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration