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 protocolNot 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

Study design

Randomised double blind active controlled parallel group trial

Primary study design

Interventional

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