ISRCTN59442355 https://doi.org/10.1186/ISRCTN59442355

Reversal of the respiratory effect of morphine and morphine-6-glucuronide by naloxone: a clinical study using healthy volunteers

Submission date
03/07/2006

Recruitment status
No longer recruiting

Registration date
04/07/2006

Overall study status
Completed

Last Edited
26/03/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N/A

Study information

Scientific Title

Reversal of the respiratory effect of morphine and morphine-6-glucuronide by naloxone: a clinical study using healthy volunteers

Study objectives
This is a pharmacological study to examine the ability to reverse respiratory depression from opioids such as morphine and Morphine-6-Glucuronide (M6G) using low-dose naloxone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received by the Ethics Committee of Leiden University Medical Center on the 6th July 2005 (ref: P04.004).

Study design
Randomised, parallel, placebo-controlled, double-blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory depression by opioids

Interventions
Measurement of respiration on a breath-to-breath basis. We will study four groups, with 12 subjects per group:
1. Group one will receive M6G 0.2 mg/ kg
2. Group two will receive M6G 0.4 mg/kg
3. Group three will receive morphine 0.15 mg/kg
4. Group four will receive morphine 0.3 mg/kg

These opioids will be administered intravenously as a bolus dose, 90 minutes after the opioid infusion, naloxone will be infused using a target controlled infusion system for one hour. Next measurement will continue for another two hours. The opioid doses to be used are based on previous studies as well on clinical efficacy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Naloxone, morphine, morphine-6-glucuronide

Primary outcome(s)
Minute ventilation and pain response to heat pain

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Healthy volunteers over 18 years of age

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Obesity (Body Mass Index [BMI] more than 30)
2. Presence of medical disease (heart, lung, liver, kidney, neurological disease, diabetes, pyrosis, diaphragmatic hernia)
3. Presence of psychiatric disease
4. History of chronic alcohol or drug use
5. Allergy to study medications
6. Possibility of pregnancy
7. Lactating females

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

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

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2010	26/03/2021	Yes	No