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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/07/2006	**Overall study status** Completed	
Last Edited 26/03/2021	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Albert Dahan

Contact details
Leiden University Medical Center (LUMC)
Department of Anesthesiology
P.O. Box 9600
Leiden
Netherlands
2300 RC
-
adahan@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Minute ventilation and pain response to heat pain

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2005

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Healthy volunteers over 18 years of age

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
CeNes Ltd (UK)

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

Study outputs

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