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Onset of analgesia with OxyNorm Instant in healthy volunteers

Submission date
19/01/2014

Recruitment status
No longer recruiting

Registration date
27/01/2014

Overall study status
Completed

Last Edited
27/01/2014

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute and breakthrough pain (sudden additional acute pain on top of the long-term pain) is difficult to treat, especially since the pain requires immediate relief. Various drugs are available with different timings of pain relief. Here we compare the effect of a new painkiller drug in the form of a melt tablet, OxyNorm instant (oxycodone formulation), with an active placebo (dummy) tablet, a paracetamol melt tablet, to assess the speed of pain relief.

Who can participate?
The study will be performed in twelve healthy female volunteers, aged 18 to 65.

What does the study involve?
Pain will be induced experimentally through electrical and pressure pain stimulus. Participants will be randomly allocated to one of two groups. For pain relief, OxyNorm instant will be given to one group and paracetamol to the other. Pain will be recorded over 5 hours following drug intake. Participants are then crossed over (i.e., the treatment is swapped). A mathematical model will be used to analyse the data and get an indication of onset of pain relief.

What are the possible benefits and risks of participating?
There will be no benefit for the participants. However, it will be useful for treating patients appropriately in future. As the drug doses are low, the risks of the study are minimal and include vomiting and itch.

Where is the study run from?
The study is run from the Leiden University Medical Center, Netherlands.

When is the study starting and how long is it expected to run for?
The study started in January 2013 and will run until February 2014.

Who is funding the study?
Mundipharma Pharmaceuticals BV, Netherlands.

Who is the main contact?
Prof. Albert Dahan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2012-002227-15

Protocol serial number
POXY/12-124

Study information

Scientific Title
A randomized cross-over study on the onset of analgesia with OxyNorm Instant in healthy volunteers

Acronym
Oxy Study

Study objectives
Oxycodone produces greater analgesia than the active comparator and meaningful analgesia, as defined by a 15% increase in response thresholds, within 10 min.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee (Commissie Mediche Ethiek), Leiden University Medical Center, Leiden, The Netherlands, 01/08/2012, Ref: P12.124

Primary study design
Interventional

Study design
Randomized placebo-controlled double-blind crossover trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Breakthrough pain

Interventions
Patients are randomised to two groups: administration of either oxycodone 20 mg or paracetamol 500 mg. Participants are then crossed over and the treatment is swapped. Antinociceptive responses to electrical and pressure pain are measured.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Efficacy is measured as a difference in pain threshold and pain tolerance scores of the OxyNorm Instant treated subjects as compared to paracetamol treated subjects at different time points
2. To determine the onset of analgesia of OxyNorm Instant. Onset of analgesia is defined as the time point at which the OxyNorm Instant treated patients display significantly increased levels of pain threshold and/or pain tolerance

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/02/2014

Eligibility

Key inclusion criteria
1. Females
2. Age of 18 to 65 years (inclusive)
3. Body Mass Index (BMI) between 18 and 35 kg/m2 (inclusive) and body weight between 50 kg and 100 kg (inclusive)
4. Subject is able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff
5. Subject is willing to comply with study restrictions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Clinically relevant abnormal history of physical and mental health, as determined by medical history taking and physical examinations obtained during the screening visit and/or prior to the administration of the initial dose of the study drug (as judged by the investigator)
2. A semi-recumbent systolic blood pressure of >150 mmHg and/or diastolic blood pressure of >90 mmHg at screening
3. History of alcoholism or substance abuse within three years prior to screening
4. Positive pregnancy test
5. Subjects using more than 14 units of alcohol per week
6. Use of medication during the study period
8. Subject is not using oral contraceptives or is not post-menopausal (last menstrual period > 2 years ago and FSH > 25 IU/L) or surgically sterilized
9. Subject has a history of severe allergies, or has had an anaphylactic reaction or significant intolerability to prescription or non-prescription drugs or food
10. Participation in an investigational drug trial in the 3 months prior to administration of the initial dose of study drug or more than 4 times per year
11. Any other condition that in the opinion of the investigator would complicate or compromise the study, or the well being of the subject:
OxyNorm is contra-indicated in case of hypersensitivity for oxycodone or one of its excipients or in any situation where opioids are contra-indicated. This can include the following situations:
11.1. Respiratory depression
11.2. Head injury
11.3. Paralytic ileus
11.4. Acute abdomen
11.5. Chronic constipation
11.6. Severe obstructive airways disease
11.7. Severe bronchial asthma
11.8. Cor pulmonale
11.9. Hypercarbia
11.10 Acute hepatic disease
11.11.Severe hepatic impairment
11.12. Severe renal impairment (creatinine clearance <10 ml/min)
11.13. Cyanosis
11.14. Concurrent administration of monoamine oxidase inhibitors or within 2 weeks of discontinuation of their use

Date of first enrolment
01/01/2013

Date of final enrolment
01/02/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Albinusdreef 2
Leiden
Netherlands
2333 ZA

Sponsor information

Organisation
Leiden University Medical Center (Netherlands)

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Netherlands)

Funder Name
Partly by Mundipharma Pharmaceuticals BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration