# Onset of analgesia with OxyNorm Instant in healthy volunteers

Submission date 19/01/2014	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 27/01/2014	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 27/01/2014	<b>Condition category</b> Signs and Symptoms	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

#### 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 a.dahan@lumc.nl

# **Contact information**

**Type(s)** Scientific

**Contact name** Prof Albert Dahan

**Contact details** Albinusdreef 2 Leiden Netherlands 2333 ZA

# Additional identifiers

**EudraCT/CTIS number** 2012-002227-15

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

#### Study design

Randomized placebo-controlled double-blind crossover trial

#### **Primary study design** Interventional

**Secondary study design** Randomised controlled trial

#### **Study setting(s)** Other

**Study type(s)** Quality of life

#### Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

#### 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 measure

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

#### Secondary outcome measures

Not provided at time of registration

Overall study start date 01/01/2013

## 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

Age group

Adult

#### Lower age limit

18 Years

Sex

Female

Target number of participants

12

#### 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)

**Sponsor details** Albinusdreef 2 Leiden

Netherlands 2333 ZA

**Sponsor type** Hospital/treatment centre Website http://www.lumc.nl

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**

**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