A randomized cross-over study on the onset of analgesia with Oxynorm Instant in healthy volunteers - the Oxy study

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To estimate the onset of analgesia of the oxycodone IR formulation OxyNorm Instant using an acute pain model in healthy volunteers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37274

Source
ToetsingOnline

Brief title
Oxy study

Condition

- Other condition

Synonym
nociception, pain

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Mundipharma

Intervention

Keyword: pain

Outcome measures

Primary outcome

Pain relief in response to a acute painful stimulus

Secondary outcome

none

Study description

Background summary

Despite the availability of various treatment strategies, the treatment of chronic pain remains a tedious and sometimes difficult task. Pharmacological interventions rely predominantly on the administration of slow-release strong opioids. While these strong opioids do take care of low intensity background pain, high intensity breakthrough pain remains a serious problem that is often difficult to treat. One option is the administration of rapidly acting opioids when breakthrough pain occurs. However, there is a large variability in the onset of analgesia between rapid acting opioids (ranging from 5 minutes to 25 min) depending on the physicochemical properties of the drug, the route of administration and the preparation (oral, sublingual, rectal, etc.). Since breakthrough pain occurs often suddenly without prior warning, knowledge on the onset of analgesia is important and consequently the choice of a specific treatment is most importantly dependent on the onset of analgesia.
Various opioids are available for the treatment of breakthrough pain in a variety of formulations and administration routes. Most of these opioids have an onset of analgesia ranging from 10-20 min. A relatively new opioid formulation is the oxycodone IR oral melt tablet, OxyNorm Instant, registered for the treatment of severe pain which requires the use of strong opioids. Although this is a simple and well acceptable method of opioid administration, also in the severely-ill patient, knowledge on the onset of analgesia is lacking. In the current study we will assess the onset of analgesia of 20 mg

Oxynorm Instant in healthy volunteers in a randomized controlled cross-over design. We will compare the OxyNorm Instant effect versus Paracetamol as this drug is available as a melt tablet as well.

Study objective

To estimate the onset of analgesia of the oxycodone IR formulation OxyNorm Instant using an acute pain model in healthy volunteers.

Study design

Randomized double-blind crossover

Study burden and risks

The burden is small. Risks or better side effects include
sedation
nausea
respiratory depression

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

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. Female 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:
• Respiratory depression
• head injury
• paralytic ileus
• acute abdomen

• chronic constipation
• severe obstructive airways disease
• severe bronchial asthma
• cor pulmonale
• hypercarbia
• acute hepatic disease
• severe hepatic impairment
• severe renal impairment (creatinine clearance <10ml/min)
• cyanosis
• concurrent administration of monoamine oxidase inhibitors or within 2 weeks of discontinuation of their use

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2012
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oxynorm instant
Generic name:	oxycodone
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Paracetamol smelttablet
Generic name:	paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-10-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-002227-15-NL
CCMO	NL40882.058.12