A randomized, placebo and active comparator (oxycodone)- controlled study on the effect of tapentadol on respiration and analgesia in healthy volunteers

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20020

Source
Nationaal Trial Register

Brief title
the Restiration study

Health condition

Opioid induced respiratory depression

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Grunenthal GmbH, Aachen Germany

Intervention

Outcome measures

Primary outcome

repsiratory depression

Secondary outcome

pain pressure treshold

Study description

Background summary

Tapentadol is a centrally acting analgesic with two mechanisms of action: a μ-opioid receptor agonism and noradrenaline (NA) reuptake inhibition. Although the binding of tapentadol to the μ-opioid receptor is weaker than that of morphine its analgesic action is similar to that of morphine due to the (synergistic) effect of the second mechanism (i.e., NA reuptake inhibition). As the effects on of opioid analgesics are attributed to μ-opioid receptor agonism, tapentadol should produce less respiratory depression at equi-analgesic doses.

Study objective

At equi-analgesia respiratory depression from oxycodone is manifold greater compared to Tapentadol

Study design

6 respiratory measurements will be obtained lasting 30 minutes at 1 hour intervals. pain tests will be obtained every half hour following administration of the study drug.

Intervention

Healthy volunteers will be administered Tapentadol in two doses, oxycodone or placebo. Hypercapnic ventilatory response curves will be obtained as well as pain pressure tests

Contacts

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Eligibility criteria

Inclusion criteria

Age of 18 to 45 years (inclusive);

Body Mass Index (BMI) between 18 and 35 kg/m2 (inclusive)

body weight between 50 kg and 100 kg (inclusive);
Subject is able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff;

Subject is willing to comply with study restrictions

Exclusion criteria

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);

A semi recumbent systolic blood pressure of >160 mmHg and/or diastolic blood pressure of > 95 mmHg at screening;

History of alcoholism or substance abuse within three years prior to screening;

Positive pregnancy test;

Positive drug screening or alcohol breath test;

Subjects using more than 21 units of alcohol per week;

Use of medication during the study period;

If sexually active, the subject is not using contraceptives, or surgically sterilized;

Subject has a history of severe allergies, or has had an anaphylactic reaction or significant intolerability to prescription or non-prescription drugs or food;
Participation in an investigational drug trial in the 2 months prior to administration of the initial dose of study drug or more than 5 times per year;

Any other condition that in the opinion of the investigator would complicate or compromise the study, or the well being of the subject:

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-02-2015
Application type:	First submission

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
NTR-new	NL4736
NTR-old	NTR5076
Other	:

Study results

Summary results
NA