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

Gepubliceerd: 06-02-2015 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20020

Bron
Nationaal Trial Register

Verkorte titel
the Restiration study

Aandoening

Opioid induced respiratory depression

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Grunenthal GmbH, Aachen Germany

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

repsiratory depression

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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:

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-02-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4736
NTR-old	NTR5076
Ander register	:

Resultaten

Samenvatting resultaten
NA