The effect of tianeptine (antidepressant) on the respiratory depression caused by painkillers

Gepubliceerd: 21-08-2013 Laatst bijgewerkt: 15-05-2024

It is hypothesized that tianeptine will prevent alfentanil‐induced respiratory depression without affecting antinociception.

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

Samenvatting

ID

NL-OMON21991

Bron
NTR

Verkorte titel
STORD

Aandoening

Opioid induced respiratory depression

Ondersteuning

Primaire sponsor: Leiden University Medical Centre
Overige ondersteuning: Revive therapeutics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the respiratory effects of an oral dose of tianeptine on alfentanil-induced

respiratory depression

Toelichting onderzoek

Achtergrond van het onderzoek

A double-blind, cross-over trial in 32 healthy volunteers to determine the influence of tianeptine (anti-depressant) on alfentanil-induced respiratory depression and analgesia

Doel van het onderzoek

It is hypothesized that tianeptine will prevent alfentanil-induced
respiratory depression without affecting antinociception.

Onderzoeksopzet

Alfentanil blood samples: baseline, 20, 50, 80, 120, 150 minutes

Vi-CO2 response baseline, after tianeptine/placebo administration, twice following start alfentanil administration (combined with tianeptine/placebo) and after stop alfentanil administration
Pain tests: (electrical and pain pressure) baseline, after tianeptine administration, twice following start alfentanil administration (combined with tianeptine/placebo) and after stop alfentanil administration

Onderzoeksproduct en/of interventie

Intravenous administration of Alfentanil by target cointrolled infusion (set to achieve a concentration of 100 ng/ml for 2 hours
Oral dose of tianeptine

a. group 1: crossover 8 subjects 37.5 mg Tianeptine/Placebo with 100 ng/ml TCI Alfentanil
b. group 2: crossover 8 subjects 50 mg Tianeptine/Placebo with 100 ng/ml TCI Alfentanil
c. group 3: crossover 8 subjects 100 mg Tianeptine/Placebo with 50 ng/ml TCI Alfentanil
d. group 4: crossover 8 subjects 100 mg Tianeptine/Placebo with 100 ng/ml TCI Alfentanil

Contactpersonen

Publiek

Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Wetenschappelijk

Leiden University Medical Center (LUMC),
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healhty volunteers (male/female)

- Age of 18 to 35 years (inclusive);

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

- Subjects using more than 20 units of alcohol per week;

- Use of medication during the study period;

- If sexually active, the subject is not using oral 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:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart

(Verwachte) startdatum:	15-09-2013
Aantal proefpersonen:	32
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40468
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3849
NTR-old	NTR4134
CCMO	NL45511.058.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40468

Resultaten

Samenvatting resultaten
N/A