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

No registrations found.

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

Summary

ID

NL-OMON21991

Source
NTR

Brief title
STORD

Health condition

Opioid induced respiratory depression

Sponsors and support

Primary sponsor: Leiden University Medical Centre
Source(s) of monetary or material Support: Revive therapeutics

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To assess the antinociceptive effects of an oral dose of tianeptine during alfentanil infusion

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

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;

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2013
Enrollment:	32
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 21-08-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40468
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A