The effect of intravenous tianeptine on an established model of opioid-induced respiratory depression (OIRD) in healthy volunteers: a population pharmacokinetic and pharmacodynamic study

Gepubliceerd: 26-07-2019 Laatst bijgewerkt: 18-08-2022

Proof of concept: to study the effect of tianeptine on opioid-induced respiratory depression in healthy volunteers.

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

Samenvatting

ID

NL-OMON24262

Bron
NTR

Verkorte titel
Tianeptine

Aandoening

healthy volunteers

Ondersteuning

Primaire sponsor: AMO UK
Overige ondersteuning: AMO UK

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In part 1 we will study the pharmacokinetics (PK) of intravenous tianeptine in 6 healthy volunteers.
In part 2 we will perform a pharmacokinetic-pharmacodynamic modeling study to assess the ability of intravenous tianeptine to reverse OIRD induced by administration of the opioid remifentanil.

In Part 1, the tianeptine plasma concentrations are the primary study end-point.
In Part 2 minute ventilation is the main study end-point.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale
The use of opioids comes with serious side effects of which opioid-induced respiratory depression (OIRD) is most dangerous. The use of drugs that antagonize OIRD but simultaneously do not affect (or even advance) analgesia would be a significant improvement over current OIRD treatment options. A possible novel option for respiratory stimulation could be with administration tianeptine. Tianeptine is an atypical antidepressant and cognitive enhancer medicine that can be administered orally or intravenously. It induces neuroplastic changes and modulates noradrenergic, dopaminergic and glutamatergic pathways. In the current experimental pharmacokinetic-pharmacodynamics modeling study we will investigate the effect of intravenous tianeptine. The study will have two parts. In part 1 we will study the pharmacokinetics (PK) of intravenous tianeptine in 6 healthy volunteers. In part 2 we will perform a pharmacokinetic-pharmacodynamic modeling study to assess the ability of intravenous tianeptine to reverse OIRD induced by administration of the opioid remifentanil (using a double blind randomized placebo-controlled design, tianeptine:placebo = 1:1).

Doel van het onderzoek

Proof of concept: to study the effect of tianeptine on opioid-induced respiratory depression in healthy volunteers.

Onderzoeksopzet

In part 1, all blood samples will be taken within 90 minutes following the start of infusion.
In part 2, continuous ventilatory measurements will be collected.

Onderzoeksproduct en/of interventie

In part 1 we will study the pharmacokinetics (PK) of intravenous tianeptine in 6 healthy volunteers. In part 2 we will perform a pharmacokinetic-pharmacodynamic modeling study to assess the ability of intravenous tianeptine to reverse OIRD induced by administration of the opioid remifentanil (using a double blind randomized placebo-controlled design, tianeptine:placebo = 1:1).

Contactpersonen

Publiek

LUMC
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Healthy male or female volunteers;
- Age: 18 - 40 years;
- Body mass index < 30 kg/m2;
- Able to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Known or suspected neuromuscular or a (family) history of any neuromuscular disease;
- A history of allergic reaction to food or medication including study medication;
- Any current or previous medical (including high blood pressure), neurological or psychiatric illness (including a history of anxiety);

- Alcohol abuse (> 21 units/week);
- History of ingestion/administration of opioids within the past 30 days;
- Illicit drug use in the past 30 days before inclusion;
- Pregnancy or lactation;
- Participation in any medical or drug trial in the month prior to the current study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-06-2019
Aantal proefpersonen:	21
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:	26-07-2019
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	NL7907
Ander register	METC Leiden Den Haag Delft : P18.249

Resultaten