

Reversal of opioid-induced respiratory depression (OIRD) by ketamine in healthy volunteers

Gepubliceerd: 28-02-2017 Laatste bijgewerkt: 18-08-2022

We hypothesize that ketamine stimulates breathing and reverses opioid-induced respiratory depression.

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

Samenvatting

ID

NL-OMON24921

Bron

Nationaal Trial Register

Verkorte titel

ORKA

Aandoening

ketamine; opioid-induced respiratory depression

Ondersteuning

Primaire sponsor: LUMC

Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- effect of ketamine on ventilation after OIRD.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a trial with a prospective double blind, placebo controlled, crossover design in healthy volunteers. The subjects will receive an intravenous infusion of remifentanil and isohypercapnic ventilation (that is ventilation at an elevated and clamped end-tidal PCO₂ aimed to increase ventilation to 20 ± 2 L/min) will be measured using a facemask.

Intravenous remifentanil will be administered by target-controlled infusion (TCI), aimed at reducing isohypercapnic ventilation by 50%. After ventilation has reached a steady state, subjects will be randomized to step wise increases in S-ketamine or placebo infusions. The S-ketamine infusion is aimed at restoring ventilation to the baseline value ($\pm 10\%$). If the baseline value is reached no further infusions are given.

On a separate occasion, we will assess the effect of ketamine on respiration by performing the step-wise increases in ketamine but without the remifentanil and without CO₂ clamping.

Doel van het onderzoek

We hypothesize that ketamine stimulates breathing and reverses opioid-induced respiratory depression.

Onderzoeksopzet

Baseline ventilation, blood sampling, Ventilatory measurements. 3 visits

Onderzoeksproduct en/of interventie

Ventilation will be elevated by isohypercapnic ventilation to 20L/min, if a steady-state is reached, there will be started with remifentanil. The ventilation will be decreased with 40-50%. After reaching steady-state again with remifentanil there will be started with ketamine or placebo

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

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);

- 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:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	21-10-2016
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	28-02-2017
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	NL6109
NTR-old	NTR6248
Ander register	NL57918.058.16 : P16.117

Resultaten