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

No registrations found.

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

Summary

ID

NL-OMON24921

Source
Nationaal Trial Register

Brief title
ORKA

Health condition

ketamine; opioid-induced respiratory depression

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

- effect of ketamine on ventilation after OIRD.

Secondary outcome

- effect of ketamine on ventilation

- arterial blood sampling for PK

- hemodynamic effect

Study description

Background summary

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 (± 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.

Study objective

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

Study design

Baseline ventilation, blood sampling, Ventilatory measurements. 3 visits

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- Healthy male or female volunteers;

- Age: 18 - 40 years;

- Body mass index < 30 kg/m2;

- Able to give informed consent.

Exclusion criteria

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2016
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6109
NTR-old	NTR6248
Other	NL57918.058.16 : P16.117

Study results