

Omkering door TRH van opiaat-geïnduceerde ademdepressie en pijnstilling in gezonde vrijwilligers

No registrations found.

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

Summary

ID

NL-OMON21474

Source

NTR

Brief title

RETRO

Health condition

opioid-induced respiratory depression

Sponsors and support

Primary sponsor: LUMC

Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

Respiratory measurements

Secondary outcome

Study description

Study objective

We hypothesize that TRH effectively antagonize opioid-induced respiratory depression

Study design

Blood samples (pre-set time points), respiratory measurements, ECG, heart rate, oxygen saturation and blood pressure

Intervention

TRH or placebo (intravenously)

Contacts

Public

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Scientific

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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:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2018

Enrollment: 15
Type: Anticipated

Ethics review

Positive opinion
Date: 18-04-2018
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	NL6966
NTR-old	NTR7154
Other	: P18.005

Study results