Feasibility and pharmacokinetics of nebulized S-ketamine inhalation in healthy adults the NebuKet study

No registrations found.

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

Summary

ID

NL-OMON23977

Source
Nationaal Trial Register

Brief title
NebuKet

Health condition

- ketamine

- nebulization

- pharmocokinetics

- analgesia

- side effects

Sponsors and support

Primary sponsor: anesthesiology department of LUMC
Source(s) of monetary or material Support: self-financing research

Intervention

Outcome measures

Primary outcome

safety of procedure

Secondary outcome

analgesia, pharmakinetics ans hemodynamic effects (Blood pressure, cardiac output, heart rate

Study description

Background summary

The aim of this study is to investigate the efficacy and safety of nebulizing S-ketamine. Three different doses of nebulized S-ketamine will be administered. Arterial blood samples will be taken to measure pharmokinetic effect. The analgesic effect will be measured by two different pain tests (pressure and electrical test). Side effects will be evaluated by two questionnaires (Bowdle, and Bond&Lader)

Study objective

- Hypothesis#1 efficacy
We hypothesize that a quick onset, and a predictable dose-response, good adjustability of analgesia can be achieved with inhaled ketamine.

Hypothesis#2 safety
Inhalation of nebulized ketamine might lead to a fast onset of analgesia, with limited adverse events.

Study design

Analgesia:before nebulization, 18, 30, 60 and 80 minutes
after start of nebulization, pain relief to pressure pain will be
studied
pharmacokinetics: arterial blood samples (3 ml per sample) for ketamine and norketamine will be taken before nebulization/iv infusion and at specific time points during and after inhalation and iv treatment.

- Hemodynamics: Continuous cardiopulmonary monitoring

-Side effects will be inquired before start of nebulization, just after and every 20 minutes after nebulization. Side
effects will be measured using visual analog scales ranging from 0 to 10 cm of the Bowdle and Bond &Lader questionnaires.

Intervention

nebulazing ketamine

Contacts

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Eligibility criteria

Inclusion criteria

men/women 18-39years BMI <30kg/m2

Exclusion criteria

pulmonary disease, hypertensin, liver/renal disease, neurological disorders diaphragmatic hernia/pyrosis, (history of) psychiatric or neurological disease, pregnancy/lactation, allergy to

study medication, (history of) illicit drug use/alcoholism; concurrent participation in another trial

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-08-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-08-2015
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	NL5210
NTR-old	NTR5358
Other	NL53147.058.15 : P15.107

Study results