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

Gepubliceerd: 11-08-2015 Laatst bijgewerkt: 18-08-2022

- 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...

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

Samenvatting

ID

NL-OMON23977

Bron
NTR

Verkorte titel
NebuKet

Aandoening

- ketamine

- nebulization

- pharmocokinetics

- analgesia

- side effects

Ondersteuning

Primaire sponsor: anesthesiology department of LUMC
Overige ondersteuning: self-financing research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

safety of procedure

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

- 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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

nebulazing ketamine

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-08-2015
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-08-2015
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	NL5210
NTR-old	NTR5358
Ander register	NL53147.058.15 : P15.107

Resultaten