Effect of Sodium NItroprusside (SNP) on R,S□] and S□]Ketamine□]induced psychotropic side effects, hemodynamic changes and pain relief in healthy volunteers

No registrations found.

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

Summary

ID

NL-OMON23422

Source
Nationaal Trial Register

Brief title
SNIK

Health condition

Psychomimetic side effects ketamine

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

psychomimetic side effects evaluated by Bowdle and Bond & Lader.

Secondary outcome

-Hemodynamic response as evaluated by mean arterial pressure and cardiac output.

- Analgesia (pressure and electrical)

-Arterial blood samples (pharmacokinetic study)

Study description

Background summary

The aim of this study is to evaluate whether the NO donor SNP prevents the occurrence of psychomimetic side effects without affecting ketamine induced analgesia.

Study objective

(1) SNP will reduce the occurrence of psychomimetic side effects during exposure to low□]dose ketamine;

(2) SNP will reduce the ketamine□]induced increase in blood pressure and cardiac output;

(3) SNP is without effect on ketamine□]induced pain relief;

(4) SNP is effective in reducing negative effects in both S□]ketamine and RS□]ketamine treated subjects.

Study design

1 hr of SNP adminstration 3 hrs of ketamine adminsitration in three concentrations. Psychomimetic side effects evaluated by questionaire will be evaluated at 15 min. intervals.

Analgesia will be evaluated at 15 min. intervals.
arterial samples will be obtained per protocol at intervals used for pharmacokinetic studies.

Intervention

Part 1: Sodium nitroprusside(SNP) or placebo will be administered intravenously started 60 minutes prior to intravenous administration of ketamine, and will be terminated when the ketamine infusion is ended. S-ketamine will be administered one hour 10mg/h, one hour 20mg/h, and one hour 40mg/h. R,S-ketamine will be administered one hour 20mg/h, one hour

40mg/h, and one hour 80mg/h.
Part 2: Ketamine (S-or R,S) will be administered intravenously 50mg/h and will be terminated after SNP is given for one hour. Concomitantly placebo infusion will be started, after one hour the placebo infusion will be replaced by SNP for one hour. (Single blinded).

Contacts

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Eligibility criteria

Inclusion criteria

Male subjects, aged 18□]34 years with a body mass index < 30 kg/m2

Exclusion criteria

Severe medical disease including hypertension, liver/renal disease, neurological disorders, diaphragmatic hernia/pyrosis; (history of) psychiatric or neurological disease; allergy to study medication; (history of) illicit drug abuse/alcoholism.

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):	20-04-2015
Enrollment:	26
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL5211
NTR-old	NTR5359
Other	NL52444.058.15 : P15.049

Study results