Fibromyalgia ketstudy

No registrations found.

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

Summary

ID

NL-OMON22499

Source
NTR

Brief title
N/A

Health condition

fibromyalgia, pain, analgesic therapy, ketamine

Sponsors and support

Primary sponsor: LUMC, department of anesthesiology
Source(s) of monetary or material Support: TREND Delft

Intervention

Outcome measures

Primary outcome

- Pain on visual analogue scale (VAS)

- Ketamine plasma concentration for PK/PK analysis

Secondary outcome

- Quality of life improvement (Fibromyalgia impact questionnaire, FIQ)

Study description

Background summary

The treatment of Complex Regional Pain Syndrome type 1 (CRPS) with S(+) ketamine showed good pain relief for weeks. Experimental pain responses returned to baseline almost immediately after the end of ketamine infusion. This suggests that ketamine might have modulatory effect on chronic pain in general. To test this hypothesis this study is designed to study its efficacy in fibromyalgia patients on pain appreciation. Furthermore this study investigate the pharmacokinetics and pharmacodynamics of (S+)-ketamine in subanaesthetic doses in fybromyalgia.

Study objective

Intravenous ketamine infusion will result in analgesia

Study design

1 intervention day after which a follow-up of 2 months, patients are asked to fill out FIQ weekly.

Intervention

Patients receive an intravenous infusion of S(+)-ketamine (0,5 mg/kg) of midazolam (5 mg) over 30 minutes in a randomised double blind fashion. Follow-up on the intervention day is 2,5 hours. During and after infusion blood samples will be drawn for PK/PD analysis. After infusion fibromyalgia pain scores, heat pain scores and scores for side effects will be obtained. After the intervention day patients will be monitored with a questionnaire.

Contacts

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Eligibility criteria

Inclusion criteria

1. Fibromyalgia according to the criteria of the American College of Rheumatology;

2. Pain NRS 5 or greater.

Exclusion criteria

1. Obesity (BMI > 30);

2. Presence of psychiatric disease;

3. History of chronic alcohol or drug use;

4. Known allergy to study medications;

5. Possibility of pregnancy;

6. Lactation

Study design

Design

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

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2010
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-06-2008
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	NL1296
NTR-old	NTR1343
Other	TREND, Delft (NL); BSIK03016 : LUMC P08.166
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A