FENTANYL-INDUCED ANALGESIA AND EFFECT OF REVERSAL BY NALOXONE

No registrations found.

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

Summary

ID

NL-OMON24927

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Pain, pain relief. Pijn, pijnbehandeling, analgesie

Sponsors and support

Primary sponsor: LUMC, Dept. of Anesthesiology
Source(s) of monetary or material Support: LUMC, Dept. of Anesthesiology

Intervention

Outcome measures

Primary outcome

Pain relief in response to a heat pain stimulus to the arm

Secondary outcome

-

Study description

Background summary

Previously, we showed that iv fentanyl produces analgesic responses in the heat pain test. This stands in sharp contrast with data from a different protocol in which we observed that another opioid (M6G) caused hyperalgesic responses using the heat pain test.

It may well be that opioids cause a balanced effect via activation of opioid and non-opioid receptors. The latter possibly being NMDA-receptors. While the analgesic effect my dominate in some opioids (due to activation of opioid receptors with little activation of NMDA receptors), other opioids may cause hyperalgesic responses due to a shift in the balance towards the NMDA-receptor activation.

In this study we will focus on this latter hypothesis. If true, all opioids will cause hyperalgesic responses when the opioid receptor is blocked. We will perform fentanyl analgesic responses with and without naloxone infusion. Furthermore we will add a placebo group allowing us to perform the study in a double-blinded fashion.

Pain will be measured using the heat pain and electrical pain tests. These methods have been shown to be very safe and previously we very successful is discerning various opioid-related phenomena, such as sex differences in opioid analgesia using these methods.

Study objective

We hypothesize that the opioid analgesic fentanyl will cause hyperalgesic responses when administered during naloxone infusion.

Study design

One session lasts 5-6 hours. Each subject will participate twice, one without and with a background infusion (naloxone/placebo)

Intervention

The study has a double-blind, cross-over, placebo-controlled design. During Session X, the subjects will receive an intravenous bolus dose of fentanyl (150 mug/70 kg) at time t = 0 during the background of an iv naloxone infusion (from t = -30 min until the end of the study; naloxone dose = 3 mg bolus followed by 3 mg/h). Next at 5-15 min intervals the response to

48-50 oC heat pain stimulus (using the TSA II device, Medoc, Israel) applied to the lower arm will be obtained. The measured response is a Visual Analogue Score (range 0 – 10 cm). During Session Y, the fentanyl infusion and heat pain measurements are identical to those of session X but now the background infusion is placebo (NaCl 0.9%). Duration of both sessions is 300 min. The sequence of session will be randomized. The naloxone/placebo treatment is blinded to the researcher and the subjects. All subjects will participate in both sessions, which will be at least 2 weeks apart.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy volunteers 18-45 years

Exclusion criteria

1. Obesity (BMI > 30)

2. Presence of medical disease (heart-, lung-, liver-, kidney-, neurological disease; diabetes

m.; pyrosis; diaphragmatic hernia)

3. Presence of psychiatric disease

4. History of chronic alcohol or drug use

5. Allergy to study medications

6. Possibility of pregnancy

7. Lactation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-03-2008
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	NL1209
NTR-old	NTR1254
Other	CME LUMC : P07.228
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A