FENTANYL-INDUCED ANALGESIA AND EFFECT OF REVERSAL BY NALOXONE

Gepubliceerd: 25-03-2008 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON24927

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Pain, pain relief. Pijn, pijnbehandeling, analgesie

Ondersteuning

Primaire sponsor: LUMC, Dept. of Anesthesiology
Overige ondersteuning: LUMC, Dept. of Anesthesiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Wetenschappelijk

Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy volunteers 18-45 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-03-2008
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	NL1209
NTR-old	NTR1254
Ander register	CME LUMC : P07.228
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A