# FENTANYL-INDUCED ANALGESIA AND EFFECT OF REVERSAL BY NALOXONE

Published: 20-11-2007
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To asses the effect of opioid receptor blockade on fentnayl induced pain relief

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32414

**Source**
ToetsingOnline

**Brief title**
Fena study

### Condition

- Other condition

**Synonym**
nociception, pain

**Health condition**

pijn

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Sponsorgelden ontvangen voor eerdere studies

## Intervention

**Keyword:** opiate, opioid, Pain, pain relief

## Outcome measures

### Primary outcome

Pain relief using two pain assays (heat pain and electrical pain)

### Secondary outcome

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# Study description

### Background summary

Previously, (Protocol P04.067) we showed that iv fentanyl produces analgesic responses in the heat pain test. See also figure 1. This stands in sharp contrast with data from a different protocol (P05.022) in which we observed that another opioid (M6G) caused hyperalgesic responses using the heat pain test (see also figure 2).

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.

### Study objective

To asses the effect of opioid receptor blockade on fentnayl induced pain relief

### Study design

Double blinded, parallel, randomized. 2 groups: A: Fentanyl vs fentanyl + naloxone// B: placebo vs naloxone + placebo

**Intervention**

Infusion of opioid (fentanyl) and its antagonist (naloxone)

**Study burden and risks**

Little to no risk. Side effect: sedation/nausea

# Contacts

**Public**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Healthy volunteers, aged 18-45 yrs

### Exclusion criteria

Obesity (BMI > 30);
Presence of medical disease (heart-, lung-, liver-, kidney-, neurological disease; diabetes m.; pyrosis; diaphragmatic hernia);
Presence of psychiatric disease;
History of chronic alcohol or drug use;
Allergy to study medications;
Possibility of pregnancy;
Lactation.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-12-2007 |
| Enrollment: | 20 |
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Fentanyl |
| Generic name: | Fentanyl |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |

| | |
|---|---|
| Brand name: | Narcan |
| Generic name: | Naloxone |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 20-11-2007 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

## 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 |
|---|---|
| EudraCT | EUCTR2007-006113-17-NL |
| CCMO | NL20439.058.07 |