# Influence of spinal deafferentation on pain threshold and offset analgesia (OA) in surgical male and female patients: the SPINAL study

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To measure offset analgesia in surgical patients before and after they received

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53706

**Source**
ToetsingOnline

**Brief title**
SPINAL study

### Condition

- Other condition

**Synonym**
Not applicable

**Health condition**

we onderzoeken geen aandoening specifiek.

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** endogenous pain modulation, offset analgesia, pain, pain perception

## Outcome measures

### Primary outcome

Pain scores on an 11-point rating scale ranging from 0 (no pain ) to 10 (most

severe pain)

### Secondary outcome

-

# Study description

### Background summary

Deafferentation or the traumatic or anesthetic disruption of afferent input from the peripheral to the central nervous system results in cortical, subcortical or brainstem reorganization and alters neuronal connectivity. In general, deafferentation causes adaptive plasticity, such as cortical expansion of brain areas adjacent to deafferentated areas, due to a rebalancing of excitatory and inhibitory neuronal modulators involved in plasticity. Deafferentation may be associated with behavioral changes. While some studies show improved acuity of motor or sensory function related to cortical plasticity, it is well known that deafferentation may additionally have negative behavioral effects related to maladaptive plasticity, as may occur in traumatic deafferentation, including phantom limb pain or pain after spinal cord injury. Spinal and epidural anesthesia are forms of short-term deafferentation. There is evidence that both types of neuraxial blockade are associated with sensory distortions or pain. In patients that require a subarachnoid or epidural block for surgery, illusionary limb position, pain in the deafferented limbs, or paradoxical heat perception upon application of a cold stimulus on the transition from normal to deafferentated skin are often observed. Additionally, in healthy volunteers, we showed that spinal deafferentation is associated with hyperalgesic responses above the level of

deafferentation coupled to
a reduction in offset analgesia. Offset analgesia (OA) is a manifestation of endogenous pain modulation. OA is characterized by profound analgesia after a slight decrease in noxious stimulation and is considered an expression of temporal filtering of nociception related to post-stimulus inhibition. See Figure 1. In Figure 2, we give the results of our prior study in volunteers.

### Study objective

To measure offset analgesia in surgical patients before and after they received

### Study design

Open intervention study (intervention is application of a noxiousstimulus)

### Intervention

Application of a noxious stimulus to the arm

### Study burden and risks

Risc and burden are nill to very light.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

All patients that will undergo an elective surgical procedure in our center

### Exclusion criteria

In case the arms of the patient do noyt allow testing on the arms.

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 200 |
| Type: | Anticipated |

# Ethics review

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|---|---|
| Approved WMO Date: | 14-02-2023 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

# 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 |
|---|---|
| CCMO | NL82861.058.22 |