# Deep and slow breathing in postsurgical abdominal pain management: an explorative study

Published: 10-03-2015
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To investigate whether deep and slow breathing exercises can reduce pain induced by mobilizing from bed to chair after major abdominal surgery, compared to a reading task.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON43878

**Source**
ToetsingOnline

**Brief title**
Deep breathing after major abdominal surgery

### Condition

- Other condition

**Synonym**
(abdominal) pain after surgery, Postsurgical (abdominal) pain

**Health condition**

Pijn na buik chirurgie

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Abdominal surgery, Analgesia, Deep and slow breathing, Pain

## Outcome measures

### Primary outcome

The primary study outcome is the Visual Analogue Scale pain score (VAS) during mobilization on the third postoperative day.

### Secondary outcome

Other parameters are: VAS during mobilization on the fourth postoperative day before intervention, VAS pain scores in rest before and after intervention, quantitative sensory testing and conditioned pain modulation parameters, cytokine and cortisol response and outcomes of pain-related psychological questionnaires (PCS, PASS and STAI). Adverse events and feasibility (MTSQ).

# Study description

### Background summary

Adequate post-operative pain management leads to less morbidity and mortality, early mobilization, shortened hospital stay, reduced costs and increased patient satisfaction. Early mobilization plays an important role in this enhanced recovery. However, reaching an adequate level of pain relief remains challenging and currently used analgesics have many side effects. Deep and slow breathing techniques (DSB) have shown hypoalgesic effects in other conditions, and may possibly contribute to post-operative analgesia.

### Study objective

To investigate whether deep and slow breathing exercises can reduce pain

induced by mobilizing from bed to chair after major abdominal surgery, compared to a reading task.

### Study design

A pilot study using a randomized controlled parallel design:
- Intervention: deep and slow breathing
- Control intervention: reading task

### Study burden and risks

The subjects participating will obtain no direct personal benefit. The results from the study will provide new insights into the possible usefulness of deep and slow breathing after surgery. The risks for the participants are negligible.

## 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

1.Patient is at least 18 years old on the day the informed consent form will be signed.
2.Patient is undergoing elective major abdominal surgery.
3.The surgical procedure has an estimated duration of at least 90 minutes, excluding the time to induce anesthesia.
4.Patient scores I to III in the American Society of Anesthesiologists physical status classification system (ASA I-III).
5.Patient is willing and able to comply with the trial protocol.
6.Patient is able to speak, read and understand the local language of the investigational site, is familiar with the procedures of the study, and agrees to participate in the study program by giving oral and written informed consent.

### Exclusion criteria

1. Severe chronic obstructive or another pulmonary disease that impairs patient from practicing deep and slow breathing
2.Patient has (a history of) a (chronic) pain syndrome that interferes with the interpretation of QST results.
3.Patient has (a history of) Raynaud syndrome or fenomenon, or a medical disorder that interferes with the study measurements or may pose a risk for the patient.
4.Patient does not feel a pinprick test to the lower extremities, due to affected sensory input (e.g. neuropathy as a result of diabetes mellitus).
5.Female patient is pregnant during the course of the study.
6.Patient is allergic to white plasters.
7. Any condition that disables the patient to make an independent transfer from bed to chair, e.g. being wheelchair bound.

## Study design

### Design

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| Study type: | Observational invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

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| Primary purpose: | Prevention |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 02-02-2016 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 10-03-2015 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 18-02-2016 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL51607.091.14 |