

# Efficacy of post-operative pain management with intralesional ropivacaine after subacromial decompression

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The research questions of this study are: 1. What is the efficacy of treatment of postoperative pain after subacromial decompression with a subacromial catheter with ropivacaine versus placebo? 2. What are the differences in costs per patient and in...

<b>Ethical review</b>	Not approved
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bone disorders (excl congenital and fractures)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON34278

### Source

ToetsingOnline

### Brief title

Pain management after subacromial decompression.

### Condition

- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

### Synonym

not enough space in the shoulder, subacromial impingement

### Research involving

Human



## Sponsors and support

**Primary sponsor:** Ziekenhuisgroep Twente

**Source(s) of monetary or material Support:** Orthopedie Centrum Oost-Nederland

## Intervention

**Keyword:** postoperative paincontrol, ropivacaine, subacromial decompression, subacromial impingement

## Outcome measures

### Primary outcome

Pain perception of the patient just after surgery and on certain moments afterwards, set on a VAS score.

### Secondary outcome

The amount of escape medication used by the patient and the calculated costs of the postoperative pain management.

## Study description

### Background summary

Patients with subacromial impingement syndrome can be treated with a subacromial decompression. This a surgery on the shoulder joint in which the impingement will be corrected. After this surgery, patients experience a lot of pain. This pain yields discomfort for the patients as well as the clinic. At the moment NSAID and opioids are used for post-operative pain management, with side effects and high costs. The relatively new painkiller ropivacaine has led to research and new applications. There hasn't been a study in which the application subacromial ropivacaine, with a catheter, after subacromial decompression is examined.

### Study objective

The researchquestions of this study are:

1. What is the efficacy of treatment of postoperative pain after subacromial decompression with a subacromial catheter with ropivacaine versus placebo?
2. What are the differences in costs per patient and in escape medication



between the patients who had a subacromial catheter with ropivacaine versus placebo after subacromial decompression?

### **Study design**

RCT with 2 groups: continuous subacromial infusion with ropivacaine versus placebo.

### **Study burden and risks**

The extra burden for the patient is that he will have an intralesional catheter, which will be removed 24 hours post-operative.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)



## Inclusion criteria

Patients (18 years and older) with subacromial impingement syndrome who need a subacromial decompression by dr. C. van Doorn

## Exclusion criteria

Significant damage at the affected shoulder or untreatable subacromial impingement  
a history of injury at the affected shoulder  
a history of surgery at the affected shoulder  
a history of mastectomy at the affected side  
a neuropathologic condition at the affected shoulder  
chronic use of opioids  
extraordinary risk-increasing factors, like morbid obesity  
Parkinsons disease  
pregnancy  
contraindications for the used medications  
disability which leads to an inability to describe pain and inability to fill in the VAS score.  
not understand written and/or spoken Dutch

## Study design

### Design

Study phase:	3
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	189



Type: Anticipated

## Medical products/devices used

Product type: Medicine  
Brand name: Naropin  
Generic name: Ropivacaine  
Registration: Yes - NL outside intended use

## Ethics review

Not approved  
Date: 20-12-2011  
Application type: First submission  
Review commission: METC Twente (Enschede)

## 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	EUCTR2010-022094-34-NL
CCMO	NL32285.044.10