‘Abduction brace versus sling after arthroscopic cuff repair‘.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22650

Source
NTR

Health condition

cuff lesion

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis
Postbus 2500
3430 EM Nieuwegein
The Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The main parameter of this study will be the difference in pain between the patients receiving an abduction brace and patients receiving a sling. This will be measured once preoperatively, eight times in the first 48 hours postoperatively, twice a day in the remaining first week and then weekly up to three months. The participants will fill in the VAS score on a 10 cm wide horizontal scale.

Secondary outcome

Secondary parameters are the Constant, ASES (only ROM part), WORC and EQ-5D score. Intra-operatively the orthopaedic surgeon will classify the size of the cuff tear according to the classification systems described by Thomazeau (stage 1-5) and by Boileau (A-F).

Study description

Background summary

Patients undergoing shoulder arthroscopy often complain of postoperative shoulder pain. There might be a correlation with the postoperative arm positioning and the pain experienced in the first postoperative weeks. In this study we compare an abduction brace with the currently used sling. Using this abduction brace, there will be less tension on the rotator cuff thereby reducing pain.

Study objective

Our hypothesize is that by using an abduction brace after arthroscopic rotator cuff repair, postoperative pain can be reduced compared with using a standard sling to immobilize te arm.

Study design

1. Pre-op;

2. Post-op: Day 1; Day 2-7; week 3; Week 6 Week 12.

Intervention

We will study the effect on pain in patients undergoing arthroscopic cuff repair comparing an abduction brace with a sling.

Group 1: Sling

The slings hold the elbow at 90 degrees, and restricts exorotation.

Group 2: Abduction brace

The brace holds the arm in 45 degrees of abduction and in neutral rotation.

Before surgery, the patient is randomized into one of the two groups, by the researcher.

The allocated group will be noted in the patient file and the orthopaedic surgeon will be informed. Surgery will be performed with the patient in the beach-chair position and under general anesthesia and a interscalene block. The surgery will be fully arthroscopic, and a double row suture bride technique will be used.

When the surgery is finished, before transferring the patient the brace of sling will be put on.

Directly after surgery, pain scores are determined at the PACU and ward. The patient is asked to keep a diary of the pain score at home on daily or weekly base in a diary.

The rehabilitation program for both groups is equal and will be communicated to their own physiotherapist by letter. The first 6 weeks they have to wear the sling or brace day and night and are advised to perform circumduction exercises at home. The physiotherapist will perform passive motions exercises to maximum 70 degrees of elevation and 20 degrees of exorotation. No active motion is allowed for six weeks or until complete recovery of passive motion had occurred. After six weeks, active motions exercises guided by the physiotherapist are allowed.

Contacts

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Eligibility criteria

Inclusion criteria

1. Cuff repair (primary procedure) for confirmed cuff lesion;

2. Subacromial decompression (optional secondary procedure);

3. Sufficient understanding of the Dutch language;

4. Competent adults;

5. Willing and able to comply to the study protocol.

Exclusion criteria

1. Age <18, >75;

2. BMI >35;

3. Diabetes mellitus;

4. Chronic pain diseases, fibromyalgia;

5. Current treatment with opiates;

6. Immunocompromized/ HIV+;

7. Labral repair;

8. Lateral clavicle resection;

9. Secondary suturing;

10. Psychiatric patients.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	01-08-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37026
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3411

Register	ID
NTR-old	NTR3554
CCMO	NL41658.100.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37026

Study results

Summary results
N/A