Transmural project for subacromial impingement syndrome: a randomized controlled trial comparing a new transmural treatment strategy (TRANSIT) with usual medical care.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22906

Source
NTR

Brief title
TRANSIT

Health condition

Subacromial impingement syndrome.

Sponsors and support

Primary sponsor: Department Orthopaedic Surgery
University Medical Center Groningen
Source(s) of monetary or material Support: Health Care Efficiency Fund
University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Shoulder Disability Questionnaire: a 16-item measure for functional status limitation in patients with shoulder disorders (Van der Heijden e.a., 2000).
Study data will be collected at the following moments: at inclusion, at randomization and three, six and twelve months after randomization.

Secondary outcome

1. Constant-Murley score;
2. Shoulder Pain Score;
3. Shoulder Rating Questionnaire;
4. Patient-perceived recovery;
5. (Dutch) Short-form 36;
6. Cost-effectiveness.

The Constant-Murley Score is a shoulder-specific scoring system in which patient-reported subjective assessment and objective measurement of shoulder function takes place (Constant e.a., 1987).
The Shoulder Pain Score is a concise questionnaire for the assessment of pain experienced by patients with shoulder complaints (Winters e.a., 1996).
The Shoulder Rating Questionnaire (SRQ-DLV) is a self-administered patient based instrument which assesses shoulder function in seven domains (Vermeulen e.a., 2005).
Patient-perceived recovery is a one-item score concerning recovery following treatment measured on a seven-point ordinal scale.
The (Dutch) Short-form 36 Health Survey is a Health-related Quality of Life Assessment system and is composed of 36 questions and standardized response choices, organized into eight multi-item scales (Aaronson, 1998).
An economic evaluation will be performed using a questionnaire for assessment of direct health care costs as well as direct non-health related costs. These data will be used for a cost-effectiveness analysis.

Study description

Background summary

Background
Subacromial impingement syndrome is commonly seen in general practice. If patients do not respond to nonoperative measures (e.g. NSAID’s, subacromial corticosteroid injections) Orthopaedic referral for acromioplasty is warranted. Results of arthroscopic subacromial decompressions presented by Diercks e.a. (1998) revealed that patients with a duration of preoperative symptoms less than one year had a significant better Constant-Murley score than patients with a duration of symptoms more than two years. Therefore the moment of

referral seems to be crucial. However, approximately 60 % of the patients recover with nonoperative measures (Morrison e.a., 1997), which has to be taken into consideration. Therefore, we designed a transmural treatment strategy which encompasses rules to diagnose and treat patients with subacromial impingement syndrome in primary care and a well defined moment of Orthopaedic referral for arthroscopic acromioplasty.
Methods
70 patients will be included in a randomized controlled trial. In general practice patients with pain on abduction of the shoulder will initially be treated according to the Guidelines for Shoulder Complaints of the Dutch College of General Practitioners (first NSAID, if necessary followed by subacromial corticosteroid injections). In case of a recurrence within 12 months following the first treatment episode with one or maximally two injections (within one month) patients will be included for TRANSIT. In case of a second recurrence within 12 months following the second treatment episode (one or two injections) the included patients will be randomized to the intervention group or the control group. The treatment will be an arthroscopic subacromial decompression within six weeks after randomization for the intervention group and usual medical care for the control group. Follow up is planned at three, six and twelve moths after randomization. The Shoulder Disability Questionnaire is our primary outcome measure. The secondary measures are: the Constant-Murley score, the Shoulder Pain Score, the Shoulder Rating Questionnaire, patient-perceived recovery, the (Dutch) Short-form 36 and an economic evaluation.
Objective
The objective of this study is to assess the effects and the costs of a new transmural treatment strategy for subacromial impingement syndrome compared to usual medical care.

Study objective

TRANSIT will give patients who have a subacromial impingement syndrome a reduced recovery time, more improvement of arm function and more reduction of shoulder pain compared to patients treated with usual medical care.

Intervention

Intervention group: the treatment is an arthroscopic subacromial decompression performed within six weeks after randomization.
Control group: the treatment is ‘usual medical care’, which consists of treatment in general practice according to the Guidelines for Shoulder Complaints of the Dutch College of General Practitioners (issued in 1999).
Both groups will be followed for one year post-randomization.

Contacts

Public
University Medical Center Groningen, Department Orthopaedic Surgery,
P.O. Box 30.001

O. Dorrestijn
Groningen 9700 RB
The Netherlands
+31 (0)50 3610078
Scientific
University Medical Center Groningen, Department Orthopaedic Surgery,
P.O. Box 30.001

O. Dorrestijn
Groningen 9700 RB
The Netherlands
+31 (0)50 3610078

Eligibility criteria

Inclusion criteria

1. Pain on abduction of the shoulder;
2. Shoulder pain as a recurrence of an episode with a maximum duration of 12 months in which a partial or good response is achieved with (a) subacromial corticosteroid injection(s);
3. A maximum duration of six months of shoulder complaints prior to the first subacromial injection, possibly treated with NSAID and/or physiotherapy;
4. No shoulder complaints for at least two years prior to the current episode of shoulder pain;
5. Men and women, age between 30 and 60 years;
6. Being able to give an informed consent.

Exclusion criteria

1. Shoulder girdle pain;
2. Shoulder pain not based on pain on abduction of the shoulder;
3. Signs of cervical root compression;
4. Bilateral shoulder pain;
5. Secondary subacromial impingement
6. Presence of specific rheumatic diseases; 7. History of severe trauma of the shoulder (fracture or luxation);
8. Previous surgery of the affected shoulder;
9. Extrinsic causes of shoulder pain;
10. Presence of dementia of other psychiatric disorders;
11. Not being able to fill in questionnaires in Dutch.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-03-2006
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-02-2006
Application type:	First submission

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
NTR-new	NL542
NTR-old	NTR586
Other	: N/A
ISRCTN	ISRCTN58108023

Study results

Summary results
N/A