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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22906

Bron
NTR

Verkorte titel
TRANSIT

Aandoening

Subacromial impingement syndrome.

Ondersteuning

Primaire sponsor: Department Orthopaedic Surgery
University Medical Center Groningen
Overige ondersteuning: Health Care Efficiency Fund
University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	08-03-2006
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-02-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL542
NTR-old	NTR586
Ander register	: N/A
ISRCTN	ISRCTN58108023

Resultaten

Samenvatting resultaten
N/A