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

**Submission date**
04/04/2006

**Registration date**
04/04/2006

**Last Edited**
20/08/2021

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[_] Record updated in last year

## Plain English summary of protocol
Not provided at time of registration

# Contact information

## Type(s)
Scientific

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# Additional identifiers

## Protocol serial number
NL542 (NTR586)

# Study information

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

## Acronym
TRANSIT

## Study objectives
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.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Subacromial impingement syndrome

## Interventions
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.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)

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

## Key secondary outcome(s))

1. Constant-Murley score - a shoulder-specific scoring system in which patient-reported subjective assessment and objective measurement of shoulder function takes place (Constant et al, 1987)
2. Shoulder Pain Score - a concise questionnaire for the assessment of pain experienced by patients with shoulder complaints (Winters et al, 1996)
3. Shoulder Rating Questionnaire (SRQ-DLV) - a self-administered patient based instrument which assesses shoulder function in seven domains (Vermeulen et al, 2005)
4. Patient-perceived recovery - a one-item score concerning recovery following treatment measured on a seven-point ordinal scale
5. (Dutch) Short-form 36 Health Survey - a Health-related Quality of Life Assessment system composed of 36 questions and standardized response choices, organized into eight multi-item scales (Aaronson, 1998).
6. Cost-effectiveness - 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.

## Completion date

01/11/2008

# Eligibility

## Key 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 three months of shoulder complaints prior to the first subacromial injection, possibly treated with non-steroidal anti-inflammatory drug (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, aged between 30 and 60 years
6. Being able to give an informed consent

Amendment to inclusion criterion number 3 as of 24/07/2006:
3. A maximum duration of six months of shoulder complaints prior to the first subacromial injection, possibly treated with non-steroidal anti-inflammatory drug (NSAID) and/or physiotherapy

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

**Sex**
All

**Key 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

**Date of first enrolment**
08/03/2006

**Date of final enrolment**
01/11/2008

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**University Medical Center Groningen**
Groningen
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# Sponsor information

**Organisation**
University Medical Center Groningen (UMCG), Department Orthopaedic Surgery (The Netherlands)

**ROR**
https://ror.org/03cv38k47

# Funder(s)

**Funder type**
University/education

**Funder Name**
University Medical Center Groningen (UMCG), Health Care Efficiency fund

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| [Protocol article](#) | Study protocol: | 22/02/2007 | | Yes | No |