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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

Recruitment status
No longer recruiting

Registration date
04/04/2006

Overall study status
Completed

Last Edited
20/08/2021

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

Primary study design
Interventional

Study design
Randomized controlled trial

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
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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