# Randomised controlled clinical trial with GRAFTJACKET® , arthroscopic, soft-tissue interposition arthroplasty as a treatment of glenohumeral osteoarthritis.

Published: 23-03-2007
Last updated: 14-05-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON30503

**Source**
ToetsingOnline

**Brief title**
GJ200609RCDH

### Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

**Synonym**
glenoid arthrosis, osteoarthritis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** onafhankelijk consultant clinical research
**Source(s) of monetary or material Support:** Wright Medical Technology;Inc;Arlington;TN ;USA

## Intervention

**Keyword:** arthroscopy, osteoarthritis, shoulder, soft-tissue

## Outcome measures

### Primary outcome

Pain (VAS) en shoulder function (via Constant score, Oxford shoulder score,

Womac, UCLA activity score)

General physical and mental health (via SF-12)

Radiographic evaluation of the osteoarthritis

MRI evaluation of the articular surfaces

### Secondary outcome

NONE

# Study description

### Background summary

When conservative treatment (analgesics, NSAIDs, corticoid injections, hyaluronic acid injections, physiotherapy,..) fails to control pain in glenohumeral osteoarthritis, surgical treatment remains the only option. However, especially in young and active patients, the surgical treatment of shoulder osteoarthritis is difficult and not always successful. Debridement, microfracturing, washout with cartilage digestive enzymes, shoulder prosthetic resurfacing, hemi- or total arthroplasty or arthrodesis have yielded variable outcomes and complications.
Based upon the promising preliminary results of soft-tissue interposition arthroplasty with an acellular allograft skin-derived collagen matrix (GraftJacket®, Wright Medical Technology, Inc. Arlington, TN, USA) in two groups of patients (first group of 11 young and active patients 1 (mean age: 50

years, range 34-68) * second group of 12 older patients with painful osteoarthritis and a reasonably good shoulder function), it was decided to set up an randomized, prospective, controlled follow-up study to assess the short-term, medium-term and long-term clinical and radiographic outcomes of this technique compared to arthroscopic glenohumeral joint debridement.

### Study objective

The primary aim of the study is the prospective recording and follow-up of the clinical and radiographic data of patients who received soft tissue interpositional arthroplasty with Graft Jacket® as a treatment of painful glenohumeral osteoarthritis in a randomised controlled study set-up comparing the outcomes with those of arthroscopic debridement.
A secondary scope of the study is to confirm the safety of the use of this acellular allograft skin-derived collagen matrix (GraftJacket®) as soft-tissue interpositional device in the shoulder, already demonstrated by the absence of device-related complications in other series .

### Study design

Design and monitoring: The GRAFTJACKET® study is a single centre, randomized, controlled, prospective, consecutive follow-up study recording the clinical and radiographic data of the soft-tissue interposition arthroplasty with GRAFTJACKET® compared to shoulder joint debridement at specific time intervals. The data will be collected using the Wright Up shoulder software.
Participating centres:
Chief investigator: Dr Pol Huijsmans, HAGA Hospital, Den Haag, the Netherlands

### Study burden and risks

NONE

## Contacts

**Public**
onafhankelijk consultant clinical research

Bosstraat 19
B-9830 Sint-Martens-Latem
BE
**Scientific**
onafhankelijk consultant clinical research

Bosstraat 19

B-9830 Sint-Martens-Latem
BE

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Painful, non-inflammatory osteoarthritis (OA) of the shoulder
2. Pre-operative radiographic confirmation of osteoarthritis of the shoulder (Kellgren-Lawrence Numerical Grading system Grade 2-4) and/or confirmation of glenoid osteoarthritis at the time of arthroscopy.
3. Patient has pain from shoulder OA not responsive to conservative treatment (NSAIDS, Analgesics, physical therapy, hyaluronic acid or corticosteroid injections): if the patient has been treated conservatively elsewhere during at least 3 months and without success, he (she) may immediately be included into the study. If the patient has not received any conservative treatment at the time of the first visit, the investigator will treat the patient with conservative measures first during three months and only include him (her) into the study in the case of persistent pain.
4. Patient is at least 18 years of age and skeletally mature.
5. Patient is otherwise in good health
6. Patient is expected to recover completely
7. Patient is willing and able to come to follow-up examinations
8. Patient has signed an informed consent

## Exclusion criteria

1. Presence of primary inflammatory arthropathy (rheumatoid, psoriatic or gouty arthritis)
2. Rapidly progressive chondrolysis of the humeral head.
3. Avascular necrosis of the humeral head
4. Infection of the shoulder joint or subacromial space.
5. Severe Rotator Cuff pathology.

6. Patient is younger than 18 years old or skeletally immature
7. Patient has a short life expectancy.
8. Patient is not willing and/or able to come to follow-up examinations
9. Patient has not signed the informed consent to record and collect his health information

# Study design

## Design

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| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-05-2007 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 23-03-2007 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# 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 |
| --- | --- |
| CCMO | NL15474.098.06 |