Difference in pain and functional outcome after arthroscopic debridement vs. debridement and biodegradable implanted balloon for irreparable rotator cuff tears.

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Primary Objective: • Is there a minimal clinical difference (NRS >2) in pain levels between subjects receiving an arthroscopic debridement with a subacromial bio-absorbable Balloon and solely arthroscopic debridement in subjects with symptomatic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON50270

Source
ToetsingOnline

Brief title
Debridement vs debridement and biodegradable balloon

Condition

- Tendon, ligament and cartilage disorders
- Soft tissue therapeutic procedures

Synonym
irreparable rupture of the muscles around the shoulder, massive rotator cuff tears

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: onderzoekstichting

Intervention

Keyword: Biodegradable balloon, debridement, rotator cuff repair, Shoulder

Outcome measures

Primary outcome

Pain measured through a Numeric Rating Scale (NRS).

Secondary outcome

-Time until the subjects receive a reversed shoulder prosthesis, if applicable

- Functional outcome measured through Oxford Shoulder Score and Total Constant

Score.

- Radiological outcome measured through Ultrascound and X-ray

-Complications

Study description

Background summary

Degenerative tears of the rotator cuff are common injuries seen in orthopaedic subjects and can give rise to pain and disability. If conservative treatment doesn*t give satisfactory decrease in pain, several surgical options for massive cuff lesions are reported. Arthroscopic debridement as well as more invasive surgery such as tendon transfers and prosthesis all give relative satisfactory results. A novel minimal invasive treatment in subjects with massive cuff lesion is the arthroscopic subacromial placement of the InSpace balloon. This biodegradable Balloon has been placed more than 2000 times worldwide up to now. In a small prospective study no implant based adverse effects have been reported and most subjects report an improvement in pain score and function (Senekovic et al. 311-16). We hypothesize that a significant difference in pain levels at 12 months post surgery are found in subjects receiving an arthroscopic debridement with a subacromial Balloon as compared to

subject who receive an arthroscopic debridement.

Study objective

Primary Objective:
• Is there a minimal clinical difference (NRS >2) in pain levels between subjects receiving an arthroscopic debridement with a subacromial bio-absorbable Balloon and solely arthroscopic debridement in subjects with symptomatic irreparable cuff tears after 1 year.

Secondary Objective(s):

• Is the progress of pain and functional outcome different and clinically relevant between the two study groups over the period of 1 year?
• What is the percentage of subject satisfaction after 1 year in the two study groups.
• What is the percentage and type of complications after 1 year?
• To compare survival rates (with endpoint reversed shoulder prosthesis) between both groups after 5 years.
*6. To compare the difference in developing osteoarthritis between the two groups after 2 years.

Study design

Prospective, double blinded, randomized, controlled study.

Intervention

The patients will be randomized in a 1: 1 ratio in the two following sub-groups:
Group 1: Subjects will undergo a surgical intervention: arthroscopic debridement and bicepstenotomie (when there was not already a rupture of the biceps tendon preoperatively)
Group 2: participants will undergo a surgical intervention: arthroscopic debridement and bicepstenotomie (when there was not already a rupture of the biceps tendon preoperatively) with subacromial balloon placement.

Study burden and risks

Since an additional X-ray picture is taken, there is the risk of radiation exposure. The total radiation exposure in this study was 0.1 mSv. By comparison, the background radiation in the Netherlands is 2.5 mSv per year. Furthermore, the patient will need to fill out additional questionnaires. This is a time load.
Furthermore, the two procedures have a risk of complications. These are described in the protocol and the patient is made aware of this by means of the

standard information leaflets.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Subject has an irreparable supra- and infraspinatus tendon tear confirmed by ultrasound or MRI and is according to the Orthopaedic Surgeon a suitable candidate for debridement.
-The symptoms of the subjects have been there for at least twelve months, despite conservative treatment, including physiotherapy, subacromial infiltration with corticosteroids or anti-inflammatory drugs.
-Subjects are older than 18 years.

Exclusion criteria

-Subject is not able to complete the daily questionnaires in Dutch.
-Subject, in the opinion of the investigator, is not able to understand this investigation and is not willing and able to perform all study procedures and co-operate with investigational procedures.
-Subject has glenohumeral osteo-arthrosis grade 3 and 4 (KELLGREN and LAWRENCE 494-502).
-Subject has a total subscalpularis tendon tear.
-Subject, in the opinion of the Investigator, is a drug or alcohol abuser (in the last 5 years) or has a psychological disorder that could affect their ability to complete subject reported questionnaires or be compliant with follow-up requirements
-Subject was diagnosed and is taking prescription medications to treat a muscular disorder that limits mobility due to severe stiffness and pain such as fibromyalgia or polymyalgia.
- Subject has an active elevation of less than 60 degrees (pseudoparalysis).
-Subject has participated in a clinical investigation with an investigational product (drug or device) in the last three months.
- Subject is allergic to the Balloon material
-Subject has a medical condition with less than 3 years of life expectancy.
.-Subject has refused voluntary, written informed consent to participate in this randomized controlled trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-01-2017

Enrollment:	104
Type:	Actual

Ethics review

Approved WMO Date:	21-10-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-08-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) 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

ID: 24952
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58522.098.16
OMON	NL-OMON24952