A randomized, two-arm, prospective, subject blind study to assess the safety and efficacy of InSpace* device in comparison to full thickness massive rotator cuff repair in subjects scheduled for a repair surgery.

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This is a post-marketing study to further assess the safety and efficacy of the InSpace* device implantation in comparison to surgical repair of full thickness MRCT . The efficacy will be assessed by comparing the pre- and post- operative shoulder...

Ethical review	Not approved
Status	Will not start
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON40993

Source
ToetsingOnline

Brief title
InSpace* in Comparison to Best Repair of Massive Rotator Cuff Tear.

Condition

- Muscle disorders

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

Research involving

Human

Sponsors and support

Primary sponsor: OrthoSpace LTD.
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: biodegradable implanted balloon, efficacy, InSpace device, rotator cuff repair

Outcome measures

Primary outcome

The primary efficacy outcome of the study is considered as the subject response rate at 6 month post-surgery or device implantation.

Subject will be defined as responder if improvement of at least 10 points of the total score from baseline (pre-operation) to 6 month follow up visit of at least one of the shoulder assessment outcome scores (ASES, Constant) is observed.

Secondary outcome

- Overall change of total shoulder outcome questionnaires scores from baseline to each follow-up visit (3w, 3m, 6m, 12m and 24m) at each treatment arm.

- Overall change in pain score from baseline to each follow-up visit (3w, 3m, 6m, 12m and 24m) at each treatment arm.

- Overall change in ADL from baseline to each follow-up visit (3w, 3m, 6m, 12m and 24m) at each treatment arm.

- Overall change in ROM from baseline to each follow-up visit (3w, 3m, 6m, 12m and 24m) at each treatment arm.

- Overall change in Quality of Life parameters (EQ-5D-5L) from baseline to each

follow-up visit (3w, 3m, 6m, 12m and 24m) at each treatment arm.

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- Time to return to work/daily activities as presented by the overall change in activity of daily living scores from baseline to each follow-up visit (3w, 3m, 6m, 12m and 24m) at each treatment arm.

- Safety assessments: Comparison of device/procedure related AEs/SAEs at each treatment arm (including re-operation rate).

- Re-tear rate at 12m as assessed by independent MRI evaluation.

- Total operation time at each treatment arm

- Subject satisfaction at 6m, 12m and 24m post-surgery.

- Descriptive presentation of the amount of required pain-relief medications at each treatment arm (based on physician assessment and ASES relevant questions) during the study follow-up period up to 12m post-surgery and comparison between the groups , if applicable.

Study description

Background summary

The incidence of Rotator cuff tears increases in frequency with age, is more common in the dominant arm, mostly to people with frequent overhead activity (painting, tennis players, construction workers etc.) and can be present in the opposite shoulder even if there is no pain. It appears that 30-40% of the population suffers from rotator cuff disease and 5-10% with clinical symptoms. In the USA, 5.4 million visits to a physician due to rotator cuff disease symptoms were done in 2004 and 250000 surgical treatments conducted in the same year.
RCTs are being classified by the size of the tear, the presence of tendon retraction, chronicity of the injury and the amount of muscle atrophy and degree of fatty degeneration. A range of surgical options are available including debridement, (with or without partial tendon repair), tendon

transfer, muscle-tendon slide procedures, the utilization of rotator cuff allograft and synthetic graft materials, arthrodesis, reverse arthroplasty or hemiarthroplasty. It has been reported in MRCTs, that primary repairs will re-rupture in between 20-65% of patients over time. Although patients with MRCTs may be capable of generating glenohumeral abduction, (with or without translation of the humeral head), methods designed to reduce pain will result in significantly improved shoulder kinematics.
Our assumption is that the deployment of an inflatable balloon into the subacromial space in patients with MRCTs will prevent impingement during abduction, resulting in painless activation of the scapulohumeral musculature. Moreover, lowering of the humeral head during balloon inflation may provide an improved balance between the subscapularis anteriorly and the infraspinatus posteriorly and permit better deltoid activation and compensation through the arc of motion .

Study objective

This is a post-marketing study to further assess the safety and efficacy of the InSpace* device implantation in comparison to surgical repair of full thickness MRCT .
The efficacy will be assessed by comparing the pre- and post- operative shoulder function as assessed by the total scores of the ASES, Constant, Quick DASH and WORC outcome questionnaires.
Overall improvement in Quality of Life parameters will be assessed using EQ-5D-5L questionnaire.

Study design

Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Subject)
Primary Purpose: Treatment

Intervention

The subjects will be randomized with a 1:1 ratio to one of the following study arms:
Arm A (Control arm) :Subjects will undergo surgical intervention (arthroscopic or mini-open procedure) to perform debridement, acromioplasty if deemed necessary, long head of biceps tenotomy, and at least partial repair of the full thickness MRCT.
Arm B (Study arm) : Subjects will undergo arthroscopic surgical intervention to perform debridement, acromioplasty if deemed necessary, long head of biceps tenotomy, and placement of the InSpace* balloon. In case sub-scapularis tear

is detected, it can be repaired prior to device implantation.

Study burden and risks

Anticipated Clinical Benefits
Potential benefits that may be realized by the subjects treated with InSpace* include favorable functional outcome of the shoulder function in terms of reduction of daily and night pain and smoother return to activity of daily living.
Another known benefit to subjects participating in any clinical study is the ability to learn more about their medical condition through the assessments that will be performed throughout the course of the study. Additionally, subjects will be closely observed by the study staff throughout their participation in the study.

Risk Analysis and Residual Risks
Risk analysis activities were performed throughout the development process and life cycle of the InSpace* device in compliance with the requirements of EN-ISO 14971 *Application of risk management to medical devices* (2012).
Prior to risk mitigation, all the risks identified were categorized as acceptable, and none were categorized as unacceptable. A comprehensive design verification and validation process, including bench tests and animal data, further demonstrates the safe and effective profile of the InSpace* device.

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

-Male or female age 40 or older
-Positive diagnostic imaging (based on MRI within 9 months of consent date) of the affected shoulder indicating full thickness Massive RCT of at least 5cm in diameter (according to Cofield classification) or long - narrow tears of at least 4cm2 (W>2cm and L>2cm) including fatty infiltration grade III or IV (according to classification of Goutallier) involving more than one tendon
-Persistent pain of the affected shoulder for at least 3 months with no response to conservative treatment (such as physical therapy, pain relief medication, local steroid injection etc.)
-Mentally and physically able to fully comply with the protocol procedures including adherence to follow-up schedule and completion of the required subject*s questionnaires.
-Willing to undergo video/photographic documentation of affected shoulder during shoulder evaluation

Exclusion criteria

-Known allergy to the device material (copolymer of PLA and -*-caprolactone)
- Evidence of severe osteoarthritis, arthropathy or cartilage damage of the shoulder with loss of passive gleno-humarel joint range of motion
- Evidence of gleno-humeral instability
-Previous surgery of the shoulder in the past 2 years, excluding diagnostic arthroscopy
-Evidence of major joint trauma, infection, or necrosis in the shoulder
-Partial-thickness tears of the rotator cuff
-Unable to provide informed consent or complete required questionnaires due to language barrier or mental status
-Major medical condition that could affect quality of life and influence the results of the study (i.e: HIV or other immunosuppressive conditions, active malignancy in the past 5 years, acute MI, CVA etc.)
-Documented or known drug or alcohol abuses that could affect quality of life and influence the results of the study
-Unwilling to be followed for the entire duration of the study

-Subjects with worker compensation claims or other litigation claims related to the shoulder being treated in the study
-Females of child-bearing potential who are pregnant or breastfeeding, or plan to become pregnant during the course of the study
-Concurrent participation in any other invasive clinical study one month prior to enrollment to the study and during the entire study period.
-The subject has implanted metallic devices (cardiac pacemakers, insulin pumps, and nerve stimulators), medically implanted clips or other electronically, magnetically or mechanically activated implants that would contraindicate undergoing an MRI scan of the shoulder
-The subject has claustrophobia that would inhibit their ability to undergo an MRI scan of the shoulder
-The subject has known allergy to the required pre-operative broad spectrum antibiotic.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	The InSpace device
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	07-07-2014
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01890733
CCMO	NL49663.098.14