postoperative immobilization in arthroscopic rotator cuff repair; the use of botulinum toxin A

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Primary objective(s): Is to determine the effect of botulinum toxin injections on postoperative pain and discomfort after an arthroscopic rotator cuff repair.Secondary: To determine whether postoperative immobilization of the rotator cuff, after...

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

Summary

ID

NL-OMON36425

Source
ToetsingOnline

Brief title
PARBO

Condition

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

Synonym
rotator cuff tear, shoulder tendon tear

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arthroscopic, botulinum toxin, immoblization, rotator cuff repair, shoulder

Outcome measures

Primary outcome

To determine whether postoperative immobilization of the rotator cuff, after arthroscopic rotator cuff repair using botulinum toxin, leads to improved postoperative pain.

Secondary outcome

To determine whether postoperative immobilization of the rotator cuff, after arthroscopic rotator cuff repair using botulinum toxin, leads to no more surgical failures than using traditional six-week sling immobilization.
Endpoint: re-tears in the supra/ infraspinatus tendon (ultra sound, mri).To determine whether postoperative immobilization of the rotator cuff, after arthroscopic rotator cuff repair using botulinum toxin, leads to improved functional outcome and strength.

To determine the difference in electrical muscle activity (EMG) and if the surgery leads to a spontaneous reversible neuropraxia.

Study description

Background summary

The general accepted postoperative protocol for rotator cuff surgery is a six-week immobilization period with the arm in resting position in a sling. The

immobilizing sling reduces the chance of failures in tendon healing by motion and gives the repair time to get strong and stable. However, it disables patients to fulfill their general daily activities and the necessary activities during work. Besides immobilization, the patients often experience a high level of postoperative pain and discomfort.
Injecting botulinum toxin A into the torn muscle causes a reversible paralysis of the muscle up to 12 weeks after arthroscopic rotator cuff repair, which should allow the patients to continue their daily activities directly after surgery, without endangering the rotator cuff repair. Herby, the patient*s discomfort will be reduced and the importance of the patient*s compliance will be less. Also, in literature botulinum toxin A is said to have a positive effect on muscle pain and might decrease the amount of postoperative pain experienced.
This study defines the possibility of using botulinum toxin as a method for postoperative immobilization.

Study objective

Primary objective(s): Is to determine the effect of botulinum toxin injections on postoperative pain and discomfort after an arthroscopic rotator cuff repair.

Secondary: To determine whether postoperative immobilization of the rotator cuff, after arthroscopic rotator cuff repair using botulinum toxin, leads to no more surgical failures than using traditional six-week sling immobilization. Showing it to be a promising new method for postoperative immobilization, it could allow patients to continue daily activities without endangering their repair.

An additional purpose is to determine difference in muscle activity in the ruptured, immobilized and repaired rotator cuff, using electromyographic analysis (EMG).

Study design

Randomized Controlled Trial

Intervention

Patients are randomized into two groups: all patients are treated for supraspinatus/infraspinatus tendon lesion using a standardized arthroscopic rotator cuff repair; Group one (control group) will receive standard postoperative immobilization (e.g. a sling for a period of 6 weeks) and group two (BTA group) consists of patients in which the supra/infraspinatus muscle are immobilized by botulinum toxine A injections. These patients are postoperatively allowed to use their shoulder functionally.

Study burden and risks

Patient burden: The burden for the participants consists of normal outpatient visits of approximately 10 minutes: preoperative, 1, 3, 6, 12 weeks, * and 1 year.
Assessment of surgical outcome; e.g. tendon integrity of the surgical repair will be performed during the six standard outpatient visits, using non-invasive and painless, ultrasound. An additional 5-10 minutes are added to total visiting time. At 6 months a MRI scan, non invasive/ harmful imaging will be performed.
In addition, the patients are asked to fill in the Oxford Shoulder Score a twelve question questionnaire: pre- and 3; 6; 12 months postoperative as well as the Constant-Murley score. The former also includes a physical examination of range of motion and strength measurements.
Postoperative pain is assessed using the Visual Analogue Scale (VAS): daily during the first week, and weekly in the second, 3rd and 6th week as well the 3rd, 6th, and 12th month.
To investigate the differences in electric muscle activity all patients in the trial will undergo fine needle EMG. This is an invasive but well established and validated technique to evaluate muscle contraction and nerve conduction. It takes up to * hour to perform and patient burden is low.

Risk/ benefit analyses: Possible risks associated with this protocol consists of side effects caused by the injection of botulinum toxin A (BTA) and the risk of a re-tear in the tendon due to tension on the repair despite immobilization of the tendon using BTA. Botulinum Toxin A is not hazardous for patients because the dose administered for therapeutic use is only a fraction of the dose required to cause dangerous systemic side effects (e.g. muscular weakness in muscles which make swallowing possible could lead to difficulties in swallowing). Other side effects described include: flu like symptoms, headache, light-headedness, chills, hypertension, diarrhea, abdominal pain. There is no evidence of organ damage caused by BTA.

Changes to the target muscles: after repeated BTA administration hypotrophy of the muscle could develop but necrotic changes or fibrotic changes have not been observed.

Based on the outcome of the pilot study, we conclude that botulinum toxin A is a promising new method for postoperative immobilization allowing patients to continue their daily activities without endangering their repair with minimum risks. This might lead to great burden reduction and freedom in movement postoperative, in a very big group of future patients in need of a rotator cuff repair.

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

- willing and able to participate in the study protocol
- age * 18 years
- symptomatic tear of the supraspinatus tendon, not responding to conservative treatment.
- male and female patients

Exclusion criteria

- hypersensitivity to Botox
- neuromuscular diseases
- diabetes
- pregnant or nursing

- aged under eighteen
- a language barrier
- mental disabilities
- additional injury as in fractures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2012
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BOTOX®100 Allergan Units
Generic name:	Botulinum Toxin type A,
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	17-06-2011
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	05-12-2014
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR30493-NL
CCMO	NL30593.098.11