Results of subacromial surgery; The influence of growth factors (PDGF), applied as autologous trombocyte concentrate, on functional recovery

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test the hypothesis that the application of PRP leads to faster wound healing, less wound healing disorders, less pain and faster functional recovery after subacromial surgery.

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

Summary

ID

NL-OMON38128

Source
ToetsingOnline

Brief title
Do growth factors improve recovery in subacromial surgery?

Condition

- Tendon, ligament and cartilage disorders

Synonym
rotator cuff rupture, subacromial impingement

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cuff, growth factors, PDGF, subacromial

Outcome measures

Primary outcome

reduce pain (VAS score)

Secondary outcome

faster functional recovery

better functional recovery

less wound healing disorders

faster work resumption

Study description

Background summary

Subacromial surgery of the shoulder is performed often. It concerns space creating interventions (open and arthroscopic subacromial decompression) and rotator cuff surgery (open and arthroscopic).
In this kind of surgery good wound healing and tissue recovery is of great importance to achieve optimal results. Wound healing disorders, pain and the formation of adhesions may negatively influnce the postoperative course and lead to extended rehabilitation. This has an infavourable influence on the personal well being of the patient and the possibility to return to labour.
Especially in cuff surgery the course is strongly influenced by the healing of the attachment of the cuff to the bone.
Besides the development of minimal invasive techniques, it's necessary to look for possibilities to decrease the morbidity of these procedures.
Recent studies show that growth factors play a major role in wound healing. This concerns particularly TFG-B (transforming growth factor B) and PDGF (platelet derived growth factor) present in thrombocytes. They act as chemotactic agents for polymorphnuclear leucocytes, macrophages, fibroblasts and lymphocytes.
Both growth factors stimulate the wound healing and cause improved angiogenesis and fibroplasie. They also play a role in wound retraction and remodelling.
In animal-experimental models it is proved that the apllication of TGF-B and

PDGF improves woundhealing and leads to better mechanical properties of the scar tissue.
Faster and better wound healing and decreased development of adhesions after subacromial surgery can possibly be influenced favourably by using thrombocyte concentrate. In the treatment with autologous thrombocyte concentrate a thrombocyte rich concentrate is obtained by a centrifuging method (Gravitational Platelet System (GPS), Biomet, Warsaw USA) (platelet rich plasma or PRP), that can be applied in the operating field. The concentrate is harvest from the patients own blood, sampled during the procedure.
At random the concentrated is apllicated and both groups are compared postoperatively.

Study objective

test the hypothesis that the application of PRP leads to faster wound healing, less wound healing disorders, less pain and faster functional recovery after subacromial surgery.

Study design

1. inclusion of the patients
2. informed consent
3. 0- measurement by preoperative score
4. randomization in the operating room
group A = application of the thrombocyte concentratein the subacromial space after wound closure
group B = control group, no application

Operative method:
- general anesthesia / regional block
- blood sampling and preparation with sterile GPS kit
- open or arthroscopic subacromial decompression
- subacromial application of the thrombocyte concntrate after skin closure (no drain is left)
- antirotating sling

The thrombocyte concentrate is obtained by taking of 55 ml of blood of the patient during schoulder surgery. With the GPS system the blood is centrifuged. After that the Platelet Rich Plasma (PRP) is stored in a sterile way. After wound closure the PRP is applicated in the subacromial space and the wound is covered.
Further treatment is identical for both groups.
control takes places on day 1 postoperatively and 2, 6, and 12 weeks postoperatively. Patients are scored on pain (VAS), mobility, ADL function (simple shoulder test), UCLA score, SF36(RAND) and Constant Murley score.

Intervention

The application of autologous trombocyte concentrate (PRP). This is a concentrate with a high amount of trombocytes (containing growth factors), obtained by centrifuging the paient's own blood. The concentrate is applied into the subacromial space after closure.

Study burden and risks

With every visit the patient is asked to fill in a questionnaire.
As far as studied, the risks are no different than the risks of the surgery

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

Age >18 years old, Given informed consent. ;And;Clinical indication for Arthroscopic Sub-acromial decompression, i.e.:
Painful arc, pain at abduction, positive Hawkinstest
Insufficient clinical improvement after (at least) 6 months of conservative treatment;or;Clinical indication for a arthroscopic cuff repair of a MRI-proven treatable rotator cuff tear.

Exclusion criteria

Coagulopathy
Thrombocytopenia
Use of corticosteroids
Diabetis Mellitus
Omarthrosis
AC-arthrosis
Cuff arthropathy
Neurological deficit at the ipsi-lateral extremity
(Wish for) Pregnancy
VAS <2 or VAS >9

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2010
Enrollment:	104

Type:	Actual

Ethics review

Approved WMO Date:	06-07-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-03-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL19106.100.07