Prospective randomized study of the effect of autologous concentrated thrombocytes versus corticosteroidinjection in lateral epicondylitis.

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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-OMON30936

Source
ToetsingOnline

Brief title
Effect of autologous thrombocytes in lateral epicondylitis.

Condition

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

Synonym
lateral epicondylitis, tenniselbow

Research involving
Human

Sponsors and support

Primary sponsor: BioMet
Source(s) of monetary or material Support: Biomet NL

Intervention

Keyword: autologous, epicondylitis, tenniselbow, thrombocytes

Outcome measures

Primary outcome

Each patient randomly assigned to a treatment and with at least one non-missing pre- and postbasdeline measurement, wiuoll be classified at each visit, as either succes or failure. Patients with a painscore reducytion>25 % cpmpared to the baseline, did not require pain medication beyond protocol defined allowable amount, and did not require escape therapy will be considerd a treatment succes.

The absolute change from baseline to endpoint means the baseline value is substracted from the endpoint value.Percent change is defined as the absolute change multiplied by 100 divided by the baseline value.

For patients whose pain improves, these values will be less than zero.

Secondary outcome

n.v.t.

Study description

Background summary

Tenniselbow, also known as lateral epicondylitis, is the most common disorder

of the elbow and is present in approximately 1.5 % of the population at any given time.
Manual workers and racket sports athletes are at high risk.
The condition typically affects patients between 35 and 50 years old.
The exact cause of lateral epicondylitis is unknown. It is assumed that that micro- and macroscopic lesions in the common origin of wrist- and fingerextensors (CEO) occur as a result of mechanical overload.
Histological specimens from chronic cases confirm that it's not an acute inflammatory condition but rather a a failure of the normal tendon repair mechanism associated with an angiofibroblastic degeneration with deposition of glycosaminoglycane, calcification an dchanges in cellmorphology. Abnormal fibroblast differentiation has an important role in the pathogenesis of tendinosis.

Injections of corticosteroids have been proven to decrease the pain temporarily and is the gold standard in the therapy of lateral epicondylitis.
However, the condition can persist for a long period of time and/or with such intense pain that alternative treatment is indicated.
Numerous methods have been advocated for treating tenniselbow. These include rest, activity restriction, bracing, physical therapy, extracorporal shockwave therapy, non-steroideal anti-inflammatory medication, corticosteroidinjections, botulism toxin injection, acupuncture etc. Howerver, few of the therapies rest on scientific evidence and none have been proven more effective than others.
An experimental treatment is the local injection of of autologous platelet concentrate obtained from a small volume of
autologous blood into the CEO.
This concept expands on the work by Edwards et al (2003) where blood was injected into the area, and directly addresses the underlying etiology.
In previous studies it has also been proven that injection of Platelet Rich Plasma (PRP) in patients with plantary fasciitis enhances repair.
The same has been proven in rats with Achilles tendon lesions.
The PRP has an 5-8 times higher concentration of platelets compared to normal blood. Platelets play an important role in the repair of tissuedamage.
They contain several growthfactors (GF) that are essential for the repair of tissue; Platelet Derived Growth Factor, Transforming GF's, Insulin like GF, Vascular Endothelial GF, Epidermal GF en Fibroblast GF. These GF can activate immature fibroblasts, as well as stimulate cellproliferation and vascular formation.
By activating the platelets several GF are released, which enhance the repair of the CEO, therefore decreasing pain.

Study objective

The objective of this study is to prove that a single injection of PRP in the

CEO decreases pain and duration of the condition in patients with chronic lateral epicondylitis compared to injection with lidocaine and corticosteroids. The specific objective is to give patients with chronic lateral epicondylitis an alternative before opting for surgical treatment.

Study design

The study is designed as a prospective reandomized study, where patients receive a single injection in the CEO. Patients will be randomly designed into one of the two treatmentgroups. The patient in the studygroup will receive an injection of buffered autologous platelet concentrate and the controlegroup of of lidocaine and corticosteroids in identical syringes.
The studywill be conducted over a period of 1 year an d contain a maximum 115 investgational with an equivalent number of control cases. All enrolledpatients will meet the inclusion criteria.
The study will continue until all study participants reach their 52-week follow-up assessment.

Study burden and risks

As with any procedure involving injection, therare risks involved with pbufferded autologous platelet concentrate for treatment of lateral epicondylitis. Potential adverse events include, but are not limited to: bleeding, infection, nerve/nervous system damage, no relief of symptoms, and worsening of symptoms. Rarely, some adverse evenets may be fatal. Thes possible adverse events are not unique to the RecoverTM kit and as stated above may occur with any procedure involving an injection.

Potential risk associated with device:
Patient participating in the study may be sunject to increased risk and/or adverse events including, but not limited to:
- pain
- deep venous thrombosis
- scar tissue formation
- reaction to Lidocaine, which could involve allergic reaction, local toxicity and potentially intravascular injection.
- thrombotic complications

Minimization of risk:
To minmaize risk, the investigational plan has defined a patientpopulation that limts exposure of the device to patients conforming to the proposed indications and in/exclusions.

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

-Men and women with lateral epicondylitis > 6 months
-Pain with palpation of the lateral epicondyl
-Pain not responding to wearing a brace or manual therapy

Exclusion criteria

-Deformities of the elbow, arthrosis, previous surgery or trauma of the elbow confirmed by X-ray(AP,lateral).
-Surgical treatment or corticosteroidinjections for lateral epicondylitis in last 6 months.
-Cervical radiculopathy or carpal tunnel syndrome in medical history.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2008
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	depo-medrol
Generic name:	methylprednisolonacetaat
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-11-2007
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-01-2008

Application type:	First submission
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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	EUCTR2006-002198-32-NL
CCMO	NL19610.008.07