Use of PRP to treat plantar fasciitis, blinded and randomized as a multi center study

Published: 11-07-2008
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To compare the efficacy of autologous platelet concentrate injections with corticosteroid injection in patients suffering from plantar fasciitis with respect to pain and function.

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

Summary

ID

NL-OMON32073

Source
ToetsingOnline

Brief title
PRP to treat Plantar fasciitis

Condition

- Tendon, ligament and cartilage disorders

Synonym
plantar fasciitis, policeman's heel

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Biomet Nederland BV

Intervention

Keyword: blood, plantar fasciitis, platelet gel

Outcome measures

Primary outcome

Pain and function measured with questionnaires

Secondary outcome

nvt

Study description

Background summary

The standard treatment of chronic plantar fasciitis is corticosteroid injections. Corticosteroid injection give temporarily pain reduction, but no healing. Blood platelets initiate the natural healing rate. GPS ® gives an eightfold concentrate platelets of patients own blood. Injection of these platelets in the tendon might induce a healing rate.

Study objective

To compare the efficacy of autologous platelet concentrate injections with corticosteroid injection in patients suffering from plantar fasciitis with respect to pain and function.

Study design

Randomized, double blinded, multi center trial

Study burden and risks

Because autologous blood is used no extra risks are expected as standard for injection in the tendon

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

> 18 years
Chronic plantar fasciitis or proximal recalcitrant heel pain (range 3-12 months)
Failed conservative treatment

Exclusion criteria

Received local steroid injections within 6 weeks, physical/occupational therapies within 4 weeks, or non-steroidal anti-inflammatories within 1 week prior
ignificant cardiovascular, renal or hepatic disease
Prior surgery for Achilles condition
Pregnant
No informed consent

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	Autologous platelet gel
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Corticosteroids
Generic name:	triamcinolon acetonide
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	11-07-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	14-07-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	27-01-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-08-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	EUCTR2008-001257-18-NL
CCMO	NL22305.008.08