

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Tendon, ligament and cartilage disorders
<b>Study type</b>	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

**Public**

Biomet Nederland BV

Hilvarenbeekseweg 60  
5000 LC Tilburg  
NL

**Scientific**

Biomet Nederland BV

Hilvarenbeekseweg 60  
5000 LC Tilburg  
NL

## 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

significant 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