long-term results of calcaneoplasty with retrocalcaneal bursectomy for patients with hindfoot pain and retrocalcaneal bursitis

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Primary Objective: The primary aim of this study is to determine the degree of patient satisfaction and assess objectively the clinical outcome at a minimum of five years follow-up after surgical intervention. Secondary Objective(s): The secondary…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Synovial and bursal disorders
Study type	Observational invasive

Summary

ID

NL-OMON43406

Source
ToetsingOnline

Brief title
Long-term follow-up retrocalcaneal bursitis(RCB)

Condition

- Synovial and bursal disorders

Synonym
bursitis, retrocalcaneal bursitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Long-term results, retrocalcaneal bursitis, surgery

Outcome measures

Primary outcome

The main study parameters are the degree of patient satisfaction.

Secondary outcome

The outcomes of the FAOS, Ogilvie-Harris scale, NRS for pain and the EQ-5D-3L.

Size of the posterosuperior calcaneal exostosis, measured on a standard lateral

radiograph using parallel pitch lines.

Study description

Background summary

The retrocalcaneal bursae can get inflamed and swollen, and this known as retrocalcaneal bursitis. This causes irritation and entrapment of the Achilles tendon and ultimately hind foot pain. When conservative treatment fails, surgical treatment is indicated. , Little is known about the long-term results of operative treatment.

Study objective

Primary Objective: The primary aim of this study is to determine the degree of patient satisfaction and assess objectively the clinical outcome at a minimum of five years follow-up after surgical intervention.
Secondary Objective(s): The secondary objective is to assess the functional outcome measures and analyse the correlation of reformation of exostosis after surgery with the recurrent or persisting complaints.

Study design

This study is designed as a retrospective case series.

Study burden and risks

All patients will receive one conventional lateral X-ray of the ankle, which is an exposure to radiation. This study does not provide immediate advantage for the participating patient.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients that underwent endoscopic calcaneoplastic surgery with bursectomy in the Academic Medical Centre (AMC) between January 1st 2000 and December 31st 2010 for the diagnosis of retrocalcaneal bursitis
- Capable of filling out a questionnaire

- Signed informed consent

Exclusion criteria

- Pregnant or possibly pregnant patients and children
- Inability to understand the patient information and the questionnaires (e.g. mental retardation, language barrier)
- No informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2016
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	19-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL55717.018.15