# Multicentric randomised trial concerning the effect of radiotherapy for painful heel spur with very low doses

<b>Submission date</b> 16/05/2007	Recruitment status  No longer recruiting	Prospectively registered		
		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/07/2007 Last Edited	Completed  Condition category	Results		
		Individual participant data		
12/08/2014	Musculoskeletal Diseases	Record updated in last year		

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Marcus Niewald

#### Contact details

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# Additional identifiers

Protocol serial number 14/07

# Study information

Scientific Title

#### Study objectives

Radiotherapy for painful heel spur with a very low dose (0.6 Gy) is as effective regarding pain relief as a standard radiotherapy with a dose of 6.0 Gy.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics committee of the Saarland Medical Association, Saarbrücken (Germany), 14/05/2007, ref: 14/07

#### Study design

Multicentric controlled randomised trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Painful heel spur

#### **Interventions**

Radiotherapy to the plantar aponeurosis and the calcaneus:

- 1. Experimental arm: total dose of 0.6 Gy in single fractions of 0.1 Gy twice weekly, total duration three weeks
- 2. Standard arm: total dose of 6.0 Gy in single fractions of 1.0 Gy twice weekly, total duration three weeks

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

- 1. 12-item Short Form health survey (SF-12): summed score, measured three months after the end of radiotherapy
- 2. Calcaneodynia summed score, measured three months after the end of radiotherapy
- 3. Visual Analogue Scale (VAS) score, measured three months after the end of radiotherapy

#### Key secondary outcome(s))

- 1. SF-12: single scores, measured three months after the end of radiotherapy
- 2. Calcaneodynia single scores, measured three months after the end of radiotherapy
- 3. Painless time interval after therapy, measured three months after the end of radiotherapy

#### Completion date

31/05/2009

# **Eligibility**

#### Key inclusion criteria

- 1. Clinical proof of a painful heel spur with a duration of anamnesis of more than six months
- 2. Radiological proof of a heel spur using conventional radiographs
- 3. Facultatively: Magnetic Resonance Imaging (MRI/MRT), ultrasound, bone scan with proof of an inflammation of the plantar aponeurosis
- 4. Typical clinical symptoms: tenderness of the calcaneus
- 5. Typical functional deficits: limitation of the distance that can be walked without pain
- 6. Aged greater than or equal to 40 years
- 7. Karnofsky performance index greater than or equal to 70%
- 8. Written informed consent

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Previous radiotherapy to the foot
- 2. Previous trauma to the foot
- 3. Additional rheumatic diseases, arterial obturation, severe venous insufficiency, lymphatic oedema of the leg involved
- 4. Pregnancy, time period of breastfeeding
- 5. Severe psychiatric disorder
- 6. Legal incapacitation

#### Date of first enrolment

21/05/2007

#### Date of final enrolment

31/05/2009

# Locations

#### Countries of recruitment

Germany

#### Study participating centre

## **Department of Radiooncology**

Homburg/Saar Germany D-66421

# Sponsor information

#### Organisation

German Cooperative Group on Radiotherapy for Benign Diseases (GCGBD) (Germany)

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Costs are covered by the clinics involved:

#### Funder Name

Saarland University Hospital (Germany)

#### Funder Name

Alfried Krupp Hospital (Alfried-Krupp-Krankenhaus Essen) (Germany)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/09/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes