

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design

Interventional

Study design

Multicentric controlled randomised trial

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