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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 [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/07/2007	**Overall study status** Completed	
Last Edited 12/08/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.benignews.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
21/05/2007

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

Age group
Adult

Sex
Both

Target number of participants
200 (100 in each arm)

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)

Sponsor details
German Society for Radiation Oncology (DEGRO)
c/o Prof. Dr med. M. Heinrich Seegenschmiedt
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Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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