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Radio surgery versus 80% phenol for toe nail matrix ablation: a randomised comparison study

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 19/08/2015	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0620171683

Study information

Scientific Title
Radio surgery versus 80% phenol for toe nail matrix ablation: a randomised comparison study

Study objectives
Does the wound heal faster when 80% phenol is used to destroy the nail-producing cells or is healing faster when radio surgery is used to destroy the nail-producing cells?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre blinded randomised comparative trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Toenail matrix ablation

Interventions
60 participants (patients who have been referred for nail surgery) will be allocated an ID number. 30 randomised to 80% phenol and 30 will receive radio surgery technique for nail matrix ablation using a random number code.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Phenol

Primary outcome measure

Healing time of the wound (to the nearest week). Pain experienced at each return visit following surgery measured using a visual scale, post-operative infection incidence measured by clinical signs and symptoms, nail regrowth incidence measured by clinical signs and symptoms, time to nail regrowth following surgery.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2005

Completion date
06/10/2007

Eligibility

Key inclusion criteria
1. Subjects will be males and females
2. Aged 18-80 years
3. They will be individuals referred to the podiatry department at the Royal Devon and Exeter Hospital (Heavitree) for nail surgery under local anaesthesia
4. They will present with a condition indicating the need for nail surgery including the following conditions:
4.1 Ingrowing toenail
4.2 Involuted nail
4.3 Fungal infection of the nail
4.4 Thickening of the nail
4.5 Severe nail hypertrophy
5. Each subject must be able to attend for follow-up visits including a 6-month visit and be able to provide informed consent
6. Participants will be happy to have their toe photographed and will be happy to be contacted by telephone after 1 year

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
2 groups of 30

Key exclusion criteria
1. Fitted with a pacemaker, artificial heart valve, artificial joints or any other type of implant because these are contra-indications to radiosurgery
2. Subungual exostosis because treatment other than nail surgery is required for this condition
3. Contraindication to anaesthesia or the procedure according to standard guidelines
4. Pregnancy or breastfeeding
5. Unable to give informed consent
6. Inadequate blood supply to the foot or toe

Date of first enrolment
01/09/2005

Date of final enrolment
06/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Podiatry
Exeter
United Kingdom
EX1 1PQ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Exeter Primary Care Trust (UK), NHS R&D Support Funding

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