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Randomised controlled trial of Taylor's versus scarf osteotomy for hallux valgus

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/07/2017	Musculoskeletal Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0234179113

Study information

Scientific Title
Randomised controlled trial of Taylor's versus scarf osteotomy for hallux valgus

Study objectives
Is there any difference in the results of surgery between two commonly performed operations for hallux valgus (bunion)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Hallux valgus

Interventions
Patients who are on the waiting list for surgery for bunions (hallux valgus) under the care of the 3 North Bristol NHS Trust foot and ankle Consultant surgeons will have an x-ray taken in the clinic. If the x-ray shows a suitable position of the bonesfor one of the two operations, and the patient is requesting surgery, then the patient will be invited to participate in the trial. It will be explained by the surgeon listing the patient for surgery.
Patients will receive an information sheet explaining the trial. If they consent to enter the trial, then they will be randomised to receive one of the two operations. Patients will be asked to complete a questionnaire with questions concerning pain and activity level. This can be completed by the patient to ensure no bias is introduced.
The operation will be performed by their usual surgical team. The postoperative care will be the same regardless of which operation is performed. Patients will be seen at 2 weeks, 6 to 8 weeks, 3 months and 1 year for clinical reviews. X-rays will be performed at 6 to 8 weeks and at 1 year.

Patients will be asked to complete a questionnaire at 1 year whilst attending the clinic. This will be the final review. Measurements will be taken from the 1 year x-ray and compared to the pre-surgery x-ray. Patient scores regarding satisfaction, pain, activity levels will be assessed from the questionnaires. Any complications will be recorded as they occur.
The review at 1 year has been chosen because by this stage the patient should have achieved the level of symptoms that they could expect long-term after surgery.
Results will be analysed using a statistical package (SPSS software).

Intervention Type
Procedure/Surgery

Primary outcome measure
Intermetatarsal angle correction (degrees)

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/01/2006

Completion date
02/01/2008

Eligibility

Key inclusion criteria
1. Hallux valgus deformity requiring surgical correction because of discomfort, pain, inability to wear appropriate footwear
2. X-rays will be measured. The intermetatarsal angle should be between 11 and 18 degrees for inclusion. This range is known as the moderate range and is felt to be suitable for the 2 operations in the trial. An angle greater than this would require a different type of operation.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Approximately 120 participants (60 per treatment group)

Key exclusion criteria
1. Inability to consent - it is non-life or limb threatening surgery, therefore patients should be able to consent to a surgical procedure
2. Age under 16 - unusual to require surgery at this age, and this would lead to consent issues
3. Multiple surgery to other toes, foot or ankle - will influence results because shape correction may be due to the other surgical procedures

4. Distal surgery required - will cause bias because not studying the same deformity and angle correction will be affected
5. Previous surgery to first metatarsal - more complicated surgery, not comparing same condition

Date of first enrolment
02/01/2006

Date of final enrolment
02/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust

Alternative Name(s)
NBT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

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