

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

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/07/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr S White

Contact details
Avon Orthopaedic Centre
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
-
simonpwhite@blueyonder.co.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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 bones for 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(s)

Intermetatarsal angle correction (degrees)

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration