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A comparison of fusion versus "half joint" replacement for arthritis of the big toe joint

Submission date
14/05/2012

Recruitment status
No longer recruiting

Registration date
21/05/2012

Overall study status
Completed

Last Edited
19/11/2018

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Arthritis of the big toe joint (hallux rigidus) results in pain, stiffness and reduced mobility. When simple measures such as pain-killers and steroid injections fail to control these symptoms, surgery is offered to patients. Currently, the gold standard treatment involves fusion (arthrodesis) of the affected joint. Whilst this gives good pain relief, patients struggle with kneeling, squatting, wearing heeled shoes and may develop arthritis at the adjacent joints. Total joint replacement surgery can maintain joint movements, but these prostheses have had problems with early loosening and failure. Replacing only one side of the joint ('half joint replacement', proximal phalanx hemiarthroplasty) has been performed and shown to give good initial results. This procedure, however, has not been compared directly with fusion surgery (current gold standard). We aim to compare fusion with 'half joint replacement' in the treatment of big toe arthritis to determine which procedure gives patients better outcomes in terms of pain and function.

Who can participate?
We are looking for patients with moderate to severe arthritis of the big toe joint (hallux rigidus) - the severity of the arthritis will be determined by both examining you and reviewing x-rays of your foot. The trial is open to males and females older than 45 years who have not become better with simple, conservative treatments. There are certain conditions that would exclude you from entering the trial - active infection, inflammatory arthritis (e.g. rheumatoid arthritis), very soft bones (osteoporosis), severe blood flow problems to the legs, any previous surgery to the big toe joint.

What does the study involve?
We are comparing two surgical procedures used in the management of big toe arthritis. Fusion of the big toe joint (arthrodesis) involves cutting out the worn out joint surfaces and then compressing the bone ends together with metal screws. When the bones heal together, there is no movement where the joint used to be and therefore no pain (but you will have stiffness from this). The second procedure is a 'half joint replacement' (proximal phalanx hemiarthroplasty). This involves cutting out only the worn joint surface from the base of the big toe and fixing in a metal replacement. This should alleviate the arthritis pain, but also allow for preserved movement at the big toe joint. We will give you specific instructions after your surgery.

Generally, you will have a dressing around the front of the foot for 2 weeks. You will be provided with a special shoe to make you walk on your heel (this prevents excessive movements at the site of surgery). You will need to use this shoe until 4 weeks ('half joint replacement') or 6 weeks (fusion). Thereafter, you will be able to walk in your normal footwear and will be referred for receive
physiotherapy. If you have a 'half joint replacement', you will receive physiotherapy earlier to start some simple exercises to move the big toe joint (this helps prevent stiffness). In total, you will be involved in this trial for 12 months from your surgery. After our final review, we will ask a few patients from each group to attend for an interview of your experience. This type of information is invaluable to us in determining if our trial process has been acceptable to you and your experiences of being in a surgical research trial. This interview will last no more than 20-30 minutes. If you agree to take part in this, we will ask you to sign a separate consent form and may use some of your statements, anonymously.

What are the possible benefits and risks of participating?
If you chose to participate in this trial, you will receive one of two established surgical procedures that are currently used in treating big toe arthritis. We do not know which procedure gives superior results. We cannot promise the study will help you directly, but the information we get might help improve how we treat arthritis of the big toe in future. Any surgical procedure has surgical risks attached to it. These risks are small, but you need to know about them. We will go over them again at the time of consenting you for the surgery. The risks common to both surgeries include:
a. Wound infection - antibiotics are given in the theatre to prevent this
b. Swelling - can persist for up to three months. Keeping your operated foot elevated will help to relieve this
c. Nerve injury - can cause numbness or pins and needles in the toe. This is usually temporary, although may persist permanently.
d. Deep Vein Thrombosis (DVT) - a blood clot in your calf muscle. These are very rare and the risk is minimised by early mobilisation. If you are at very high risk, we will supply you with injections to thin your blood for 2 weeks after your surgery to minimise this risk
e. Scar sensitivity - this usually settles within 6 months
f. Ongoing symptoms - we cannot guarantee that your symptoms will be 100% improved
Additionally, the following risks are special to fusion surgery:
a. Delayed or failed fusion - the risk of this is about 5-10%. Smoking and some medications can delay bone healing. Unsuccessful fusions may require further surgery.
b. Removal of screws - occasionally, the metalwork can cause symptoms if prominent and may need to be removed
'Half joint replacement' surgery has these extra risks:
a. Stiffness - your big toe should move better after this surgery. You may need on-going physiotherapy to work on any residual stiffness
b. Loosening - with time, the prosthesis may begin to loosen. This will depend on how heavy you are and the type of activity you engage in. You may require fusion surgery in the future if it were to loosen.

Where is the study run from?
This trial will be run in the East Lancashire Hospitals NHS Trust. Clinical follow-up appointments will be performed at Royal Blackburn Hospital. All elective surgery is performed at Burnley General Hospital.

When is the study starting and how long is it expected to run for?
We aim to start recruiting patients from October 2012. We hope to recruit enough patients by February 2013. The trial will end after all patients have completed a 12 month follow-up period, roughly July 2014.

Who is funding the study?
British Orthopaedic Association and the British Orthopaedic Foot & Ankle Society for grants to fund this trial

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
2012/017

Study information

Scientific Title
First metatarsophalangeal arthrodesis versus hemiarthroplasty for hallux rigidus: a pilot study

Study objectives
To compare the functional outcomes between first metatarsophalangeal joint arthrodesis with proximal phalangeal hemiarthroplasty in the treatment of hallux rigidus

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East NRES, 15/01/2013, ref:12/NE/0385

Study design
Single-centre prospective randomised controlled assessor-blinded pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hallux rigidus (osteoarthritis of the first metatarsophalgeal joint)

Interventions
1. Arthrodesis of the first metatarsophalgeal joint (active control group)
2. Proximal phalanx hemiarthroplasty (AnaToemic prosthesis, Arthrex Inc)

Participants in both study groups will be followed up for 12 months from surgery

Intervention Type
Procedure/Surgery

Primary outcome(s)
Manchester - Oxford Foot Questionnaire (MOX-FQ) - measured at baseline then at 6 weeks, 3 months and 12 months post-operatively.

Key secondary outcome(s))
1. EuroQol (EQ-5D)
2. Pain visual analogue scale (0=no pain, 10=unbearable pain)
3. American Orthopaedic Foot & Ankle Society Hallux score (AOFAS-Hallux)
4. Hospital length of stay
5. Return to work
6. Complication rate
7. Re-operation rate (failed procedure, removal of metalwork)

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Coughlin grade 3-4 hallux rigidus with near constant pain and stiffness at least at extremes of passive motion +/- mid range of motion pain, in whom conservative treatment measures have failed
2. Able to give informed consent
3. Male or female
4. Aged 45 years or above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Inflammatory Arthritis
2. Active Infection
3. Severe vascular or neurological deficit affecting the lower limbs
4. Hallux Valgus angle greater than 15 degrees
5. Inadequate or poor quality bone stock
6. Any previous surgery to the 1st MPTJ other than a cheilectomy
7. Significant and symptomatic interphalangeal joint or sesamoid-metatarsal osteoarthritis

Date of first enrolment
01/10/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Lancashire Hospitals NHS Trust
Blackburn
United Kingdom
BB2 3HH

Sponsor information

Organisation
East Lancashire Hospitals NHS Trust (UK)

ROR
https://ror.org/002pa9318

Funder(s)

Funder type
Charity

Funder Name
British Orthopaedic Association (UK) ref: GA1215

Alternative Name(s)
, BOA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
British Orthopaedic Foot & Ankle Society (UK)

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	13/03/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes