ISRCTN91428492 https://doi.org/10.1186/ISRCTN91428492

Hallux Rigidus Minimally invasive Trial comparing minimally invasive cheilectomy of the great toe metatarsophalangeal joint with open cheilectomy

Submission date
13/03/2012

Recruitment status
No longer recruiting

Registration date
18/04/2012

Overall study status
Completed

Last Edited
15/03/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Cheilectomy is a surgical procedure which is performed for painful arthritis of the big toe joint. The aim of the surgery is to provide pain relief and to delay or prevent the arthritis getting worse. There are two methods for performing the surgery: open cheilectomy and minimally invasive cheilectomy. Currently there is no published evidence to suggest which procedure is best. Open cheilectomy has been used for 25 years and is a well-established procedure. Minimally invasive cheilectomy is a new procedure which is only available in a small number of centres in the UK and has less well-known results. Open cheilectomy uses a 5 cm cut in the skin over the side of the big toe to remove the painful bump and clear out the joint. Minimally invasive cheilectomy uses a very small drill-like device called a burr to remove the bump from the toe joint. This may be introduced through a very small hole without the need for a larger cut in the skin. The aim of our study is to decide which method of doing the operation is the best in terms of how well patients are able to get back to normal life after the surgery.

Who can participate?
Patients will be eligible to participate if they are between 18 and 90 years old, have symptomatic arthritis of the great toe and have decided they would like surgery for this.

What does the study involve?
Patients deciding to take part will be attend a pre-operative planning session with our trial researcher and consultant surgeon. They will talk through the plans for surgery and answer any questions about the trial. On the day of surgery patients will be randomly allocated to undergo either minimally invasive cheilectomy or open cheilectomy. Patients will be unaware of which group they are in. After the surgery patients complete a diary of the pain from the big toe daily for two weeks. We subsequently review patients in our clinic at 6 weeks, 3 months, 6 months and 1 year after surgery. Each time patients are seen in clinic they will be assessed by our trial researcher who will examine the toe and ask set questions from a questionnaire about problems after the surgery and any residual pain.

What are the possible benefits and risks of participating?
Both surgeries are small procedures which are relatively low-risk. However, all surgeries carry risks and these include a risk of infection in the joint, ongoing pain or stiffness, nerve damage and problems with wound healing and scar formation. Minimally invasive cheilectomy is a new technique which preliminary studies have shown to be safe. There could be a complication of this surgery which we are not aware of. As part of the study group patients will be required to attend the hospital for two extra visits in addition to normal follow-up. This allows us to assess the progress of the toe during the year after your surgery. We are unfortunately unable to reimburse travel expenses for these journeys.

Where is the study run from?
The study is run from Torbay Hospital (UK).

When is study starting and how long is it expected to run for?
The study is starting in March 2012 and is expected to run for 5 years.

Who is funding the study?
The study is funded by a grant from the Torbay Medical Research Fund (UK).

Who is the main contact?
The research is being organized by James Davis, Consultant Foot and Ankle surgeon. His secretary is available via Switchboard at Torbay Hospital (01803614567) and should be the main contact for enquiries about this trial.

Contact information

Type(s)
Scientific

Contact name
Mr James Davis

Contact details
Directorate of Trauma and Orthopaedics
Torquay Hospital
Lawes Bridge
Torquay
United Kingdom
TQ26AA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V2.0

Study information

Scientific Title
Minimally invasive vs open cheilectomy: A single-blinded randomised controlled trial

Acronym
HRMiT

Study objectives
To determine whether there is more rapid improvement in foot function following minimally invasive cheilectomy than with open cheilectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research and Ethics Committee South-West (Exeter) approved on 09/11/2011, Ref: 11/SW /0218

Study design
Single-blinded 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
First metatarsophalangeal joint arthritis

Interventions
Patients randomised to minimally invasive or open cheilectomy

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The American Orthopaedic Foot & Ankle Society (AOFAS) hallux metatarsophalangeal-interphalangeal scale is a validated and widely used tool for assessing forefoot function. The score rates first metatarsophalangeal / interphalangeal function out of 100 points where 100 is the best possible score. Measured pre-op, 6 weeks, 3 months, 6 months and 1 year post-surgery.

Secondary outcome measures
1. Manchester Oxford Foot Questionnaire (MOXFQ) (3). This is a relatively new patient-based questionnaire which has been evaluated in the context of hallux valgus surgery and previously used to assess the outcome of cheilectomy. The score consists of three domains [Pain (7 questions), Walking (4 questions) and Social interaction (4 questions)] and is assessed using a structured questionnaire with the results are expressed as a metric value between 0 and 100
2. Time to return to normal shoes
3. Time to return to employment
4. Visual analogue pain scores
5. Re-operation rate
Measured pre-op, 6 weeks, 3 months, 6 months and 1 year post-surgery. Patients will also complete a pain diary for 14 days after surgery.

Overall study start date
10/03/2012

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Patients over the age of 18 and under the age of 90
2. Patients undergoing primary surgery
3. Patients who are able to give informed consent to the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Patients less than the age of 18 and over the age of 90
2. Patients who are not undergoing primary surgery
3. Lack of capacity to give informed consent

Date of first enrolment
10/03/2012

Date of final enrolment
10/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Directorate of Trauma and Orthopaedics
Torquay
United Kingdom
TQ26AA

Sponsor information

Organisation
Torbay Hospital (UK)

Sponsor details
Research and Development Department
Horizon Building
Lawes Bridge
Torquay
England
United Kingdom
TQ26AA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01vv3y523

Funder(s)

Funder type
Charity

Funder Name
Torbay Medical Research Fund (UK) Ref:104

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