ISRCTN17635882 https://doi.org/10.1186/ISRCTN17635882

Comparing open and minimally invasive osteotomy for the surgical correction of bunions - a feasibility study

Submission date
19/09/2016

Recruitment status
No longer recruiting

Registration date
02/11/2016

Overall study status
Completed

Last Edited
22/03/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Hallux vulgaris, more commonly known as a bunion, is a bony deformity of the joint at the base of the big toe at the side of the foot. Although some people never experience any symptoms, many people suffer for years with bunions, as pressure from shoes against it can cause pain and discomfort. An operation to correct the deformity may be offered, if non-surgical treatments do not cause any relief. Bunion correction surgery has traditionally been performed by making an approximately 15cm long cut on the inside of the foot, known as an 'open procedure' with good results. Over recent years, there has been a move to achieve the same results of surgery though small keyhole incisions, known as a 'minimally invasive procedures'. The aim of this study is to discover whether patients have a preference for the type of bunion surgery they have, and to discover whether one surgical technique produces better results for patients than the other.

Who can participate?
Adults with bunions suitable to be corrected by either an open procedure or by a minimally invasive procedure.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have an open surgical procedure, and those in the second group have a minimally invasive surgical procedure. Before surgery, participants in both groups are asked to fill out a questionnaire and the range of movement in the joint is measured. The advice and regime following surgery are exactly the same whichever surgical procedure has been performed. The foot has a dressing applied and is placed in a heel weight bearing shoe. Participants then attend an appointments two weeks later so that the dressing can be removed and to check the wound and be placed in a light splint inside the heel weight bearing shoe, at this stage participants are encouraged to get the toe moving. Six weeks and then six months after surgery, participants have the range of movement in the joint measured again. One year after surgery, participants are contacted by a research nurse by telephone to complete a questionnaire.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in the study. However, it is hoped that the information obtained from the study will help further research in bunion surgical procedures. Both procedures are currently performed in routine practice within the NHS. The main complications or risks of surgery are common to both procedures. These include wound infection, fracture, pain, failure of fixation, removal of metalwork in the future and recurrence of the deformity. One of the aims of the study is to help find out which procedure is best tolerated and of lower risk to patients.

Where is the study run from?
1. North Tyneside General Hospital (UK)
2. Hexham Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2017 to September 2020

Who is funding the study?
Northumbria Healthcare NHS Foundation Trust (UK)

Who is the main contact?
1. Mrs Deborah Bunn (public)
2. Mr Nicholas Hutt (scientific)

Contact information

Type(s)
Public

Contact name
Mrs Deborah Bunn

Contact details
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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16/NE/049

Study information

Scientific Title
COSMIC study - Comparing Open Scarf osteotomy and Minimally Invasive Chevron for Hallux Valgus Correction. A Feasibility Study

Acronym
COSMIC

Study objectives
The aim of this study is to assess the feasibility of conducting a study to compare the patient recorded and clinical outcomes for the surgical management of Hallux Valgus correction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Tyne and Wear South Research Ethics Committee, 08/04/2016, ref: 16/NE/0049

Study design
Prospective randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied
Hallux Valgus

Interventions
Participants will be identified in outpatient clinics and offered to participate in the study. Pre-operative patient questionnaires will be recorded. The patients will then be randomized into one of the treatment arms for their surgical intervention.

Group 1: Participants undergo Open Scarf/Akin osteotomy. A Scarf osteotomy is performed through an open incision. A Z shaped osteotomy of the metatarsal which allows lateral translation and therefore correction of the hallux valgus deformity. This is fixed with 2 screws. This is combined with a lateral soft tissue release and is also often accompanied by an Akin osteotomy, a medial closed wedge osteotomy of the proximal phalanx of the great toe that corrects hallux valgus interphalangeus and improves the cosmetic result.
Group 2: Participants undergo Minimally Invasive Chevron/Akin osteotomy. Through a minimally invasive approach, a lateral release is performed. Then an extracapsular chevron osteotomy is performed allowing lateral translation and therefore correction of the deformity. This is held in place by 2 screws. This is often performed with a minimally invasive Akin osteotomy held with screw fixation.

Post-operative care and rehabilitation will follow the same program in both arms as follows:

0-2 weeks:
Placement in weight bearing heel rocker post op shoe
2 weeks:
Wound check in dressings clinic and placement of Darco Splint, Instructions on mobilization of 1st Metatarsal Phalangeal Joint
6 weeks:
Out patient clinic review Begin mobilizing in normal footwear with Darco Splint, continue mobilization of 1st MPTJ.
Range of movement of 1st MTP recorded
6 months:
Final Outpatient Clinic review (including range of movement of 1st MTP and Patient Reported Outcome Questionnaire)
12 months:
Questionnaire by telephone or post

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary outcome measure is feasibility of the study. This will be assessed via the number of patients able to be recruited into the study. Retention of those patients throughout the study and from analyzing the initial data, discussed in secondary outcome measures, to assess if any concerns are raised during the study period.

Secondary outcome measures
1. Patient reported outcomes - This outcome measure will be the patient reported outcomes obtained by patient questionnaire. MOXFQ-index will be obtained from patients' questionnaires

pre operatively for baseline and subsequently at 6 and 12 months for both groups
2. Range of movement of the 1st MTPJ will be measured with a goniometer preoperatively and at Outpatient follow up and 6 weeks and 6 months. The differences between the two groups will be statistically analyzed
3. Adverse Events are recorded through clinical observations throughout the post-operative period

Overall study start date
16/04/2015

Completion date
13/09/2020

Eligibility

Key inclusion criteria
1. Patients over 18 years of age
2. Patients with Hallux valgus deformity suitable for treatment by both Open Scarf/Akin and MICA procedures
3. Patients with no significant co-morbidities that would increase their risk of procedure
4. Patients able to understand and complete questionnaires
5. Patients with the capacity to provide informed consent
6. Patients who have in addition to Hallux Valgus deformity, have lesser toe deformities requiring correction distal to the metatarsal phalangeal joint at time of procedure
7. Patients without significant other mid foot or hind foot pathology

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 patients approached

Key exclusion criteria
1. Patients under 18 years of age
2. Patients with severity of Hallux valgus deformity necessitating Open procedure
3. Patients with significant co-morbidities that would increase the risk of surgery
4. Patients unable to understand or complete questionnaires
5. Patients without the capacity to provide informed consent
6. Patients with additional deformity requiring additional procedures proximal to the metatarsal phalangeal joint

Date of first enrolment
13/09/2017

Date of final enrolment
13/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Hexham Hospital
Corbridge Road
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NE46 1QJ

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust,

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Northumbria Healthcare NHS Foundation Trust

Results and Publications

Publication and dissemination plan
Presentation at international Foot and Ankle conference and planned publication in a high-impact peer reviewed journal within one year of trial end date.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	23/03/2016	02/11/2016	No	Yes
HRA research summary			28/06/2023	No	No