# Fusion surgery for bunions gives improvement in pain and function

<b>Recruitment status</b> No longer recruiting	Prospectively registered     Protocol
<b>Overall study status</b>	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Condition category	<ul> <li>Individual participant data</li> <li>[X] Record updated in last year</li> </ul>
	Recruitment status To longer recruiting Overall study status Completed Condition category Ausculoskeletal Diseases

#### Plain English summary of protocol

Background and study aims:

Hallux valgus (HV) is a painful deformity of the big toe/forefoot, also known as a bunion. There are multiple surgical options for its management, including fusing the joint at the base of the big toe (first metatarsophalangeal joint [MTPJ] arthrodesis). In our institution, this procedure is preferred over corrective osteotomy for patients with severe HV. This study aimed to investigate the outcomes of patients undergoing first MTPJ arthrodesis for HV.

Who can participate? Patients aged over 16 years undergoing arthrodesis for HV between 2016 and 2021 in NHS Tayside

What does the study involve?

Participants complete questionnaires about their health and function before surgery and at 26, 52 and 104 weeks after surgery.

What are the possible benefits and risks of participating? The study will identify whether first metatarsophalangeal joint fusion is a safe and effective treatment for hallux valgus.

Where is the study run from? NHS Tayside (UK)

When is the study starting and how long is it expected to run for? January 2021 to June 2022

Who is funding the study? Investigator initiated and funded

Who is the main contact? Miss Rebecca Lewis, rebecca.lewis@nhs.scot

## **Contact information**

**Type(s)** Public, Scientific, Principal Investigator

**Contact name** Miss Rebecca Lewis

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# Additional identifiers

EudraCT/CTIS number Nil known

**IRAS number** 

**ClinicalTrials.gov number** Nil known

**Secondary identifying numbers** Nil known

## Study information

#### Scientific Title

First metatarsophalangeal joint arthrodesis for hallux valgus gives satisfactory patient-reported outcomes: a retrospective case series

#### **Study objectives**

Arthrodesis for hallux valgus in the absence of radiological evidence of degenerative joint disease results in improvements in patient-reported outcome measures.

#### Ethics approval required

Ethics approval not required

#### Ethics approval(s)

Ethical approval was not sought for this study because it was a retrospective evaluation of local clinical practice and, therefore, not deemed to require ethics committee approval. Caldicott permission was sought and granted.

**Study design** Single-centre observational case series

**Primary study design** Observational

**Secondary study design** Case series

**Study setting(s)** Hospital

**Study type(s)** Treatment, Efficacy

**Participant information sheet** Not applicable

Health condition(s) or problem(s) studied

Hallux valgus

#### Interventions

The researchers will conduct a single-centre case series design with prospectively collected Patient Reported Outcome Measures data and retrospective case note review. Data will be requested from the local Foot and Ankle database. For each patient, the primary pathology of HV will be confirmed using preoperative radiographs and first MTPJ arthrodesis will be confirmed using the operative notes. After confirming these details, all patients who have completed preoperative PROMs and had their operations between January 2016 and July 2021 will be included. Patients will be excluded based on inadequate operative information, in cases where arthrodesis cannot be confirmed, and patients whose primary pathology is degenerative disease, apparent on preoperative radiographs. Some patients will have undergone simultaneous bilateral arthrodesis or additional concurrent procedures involving the first ray or lesser metatarsals; to reflect clinical practice, these patients will be included. Finally, patients will not be excluded because of rheumatoid arthritis if HV is still considered the primary pathology. Instead, patients with rheumatoid and diabetes mellitus will be considered during analysis.

#### Intervention Type

Procedure/Surgery

#### Primary outcome measure

1. Pain is measured using the Manchester-Oxford foot questionnaire (MOxFQ) and the EQ-5D-5L questionnaire at baseline, 26, 52 and 104 weeks postoperatively

2. Walking-standing ability is measured using the Manchester-Oxford foot questionnaire (MOxFQ) at baseline, 26, 52 and 104 weeks postoperatively

3. Social interaction is measured using the Manchester-Oxford foot questionnaire (MOxFQ) at baseline, 26, 52 and 104 weeks postoperatively

4. Overall health is measured using the EQ-5D-5L visual analogue score (VAS) at baseline, 26, 52 and 104 weeks postoperatively

#### Secondary outcome measures

Complication rates, including non-union, pain, reoperation, infection and delayed wound healing. This data will be collected at the end of the study period.

Overall study start date

01/01/2021

Completion date

30/06/2022

# Eligibility

#### Key inclusion criteria

Aged over 16 years
 Undergone first MTPJ arthrodesis for hallux valgus between January 2016 and July 2021

**Participant type(s)** Patient

**Age group** Adult

**Lower age limit** 16 Years

**Sex** Both

**Target number of participants** 60

**Total final enrolment** 62

**Key exclusion criteria** Patients with inadequate operative information.

Date of first enrolment 22/01/2016

Date of final enrolment 10/06/2021

### Locations

**Countries of recruitment** Scotland

United Kingdom

**Study participating centre NHS Tayside** Ninewells Hospital Dundee United Kingdom DD3 8EA

## Sponsor information

**Organisation** NHS Tayside

**Sponsor details** Ninewells Hospital Dundee Scotland United Kingdom DD1 9SY

**Sponsor type** Hospital/treatment centre

Website http://www.nhstayside.scot.nhs.uk/index.htm

ROR https://ror.org/000ywep40

# Funder(s)

**Funder type** Other

**Funder Name** Investigator initiated and funded

# **Results and Publications**

**Publication and dissemination plan** Planned publication in a peer-reviewed journal

#### Intention to publish date

01/09/2025

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection & patient confidentiality.

#### IPD sharing plan summary

Not expected to be made available