A DARFI Study
Into
Fractures of The Talus
(FACT-1)

Study lead: Mr Edward Gee

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Background

Study Management Group

Mr Edward Gee

Mr Abdul Rahman Gomaa

Mr Lyndon Mason

Mr Thomas Rogers

Mr Lyndon Mason (via the research fellow) will ensure that LUHFT's local research governance committee is regularly updated with the study's progress.

Final approval for new study sites to commence data collection and upload will be authorised by LUHFT's R&I once all site has issued confirmation of capacity and capability.

Scientific Advisory Group

Mr Donatas Chlebinskas

Mr Howard Davies

Mr Paul Fenton

Mr Edward Gee

Mr Abdul Rahman Gomaa

Mr Lucky Jeyaseelan

Mr Dev Mahadevan

Mr Jitendra Mangwani

Mr Lyndon Mason

Mr Matt Philpott

Mr Andy Riddick

Mr Pete Robinson

Miss Mona Theadoraki

Mr Alex Trompeter

Mr Bobby Siddiqui

Study Delivery Timeline

From the point of launch:

4 months for data collection

6 months to preliminary data assessment

8 months to presentation

12 months to publication

Executive Summary

To ascertain the true risk factors for the management of talar fractures. By collecting a large population from multiple national centres treating this rare, complex injury we hope to accurately assess the risk factors for non-union, avascular necrosis, collapse, early arthritis and further surgery in the first 18 months post injury.

About DARFI

The Database of Atypical and Rare Fractures and Injuries (DARFI) is a collaborative platform for the study of atypical and rare fractures and injuries on a national scale to better understand their epidemiology and improve their outcomes.

Introduction

Talar fractures carry high rates of complications and morbidity, namely non-union, avascular necrosis, mal-reduction and early arthritis. These injuries often occur in a young, active population with significant impact on quality of life and morbidity. Complications pose a challenging clinical situation, and rates vary greatly between papers. Evidence is often underpowered due to this being a relatively rare injury. To combat this power is increased by performing met-analyses, systematic reviews or studying a cohort over a large time period, during which significant changes in management, techniques and implants may have rendered previous management strategies obsolete.

Study Aims

We aim to perform a multi-centre, retrospective review of talus fractures treated within the past 10 years using a national collaborative (FACT). This should enable a well powered study talus fractures with a variety of managements and complications. We aim to identify specific risk factors for current complication rates to guide best management.

Methods

The study will run from 15th February 2026 to 12th June 2026. Centres will enrol to be included in FACT1. Data will be collected by registrar or consultant level orthopaedic surgeons.

Data will be collected retrospectively by enrolled centres using their hospital's electronic and paper notes. Patients treated between 1st January 2013 and 28th February 2026 (minimum 3 month follow up) will be included. We aim for a study population of over 250 patients nationally.

Patient details will be pseudonymised and centres will keep a list of which the pseudonymised number correlates to which patient locally. This list will be kept in a secure file locally by each site's PI.

Inclusion criteria

Any talar fracture in adult 16+ between 1st January 2013 and 28th February 2026 with minimum of 3 month follow up

Exclusion criteria

Patients that are excluded via the National Data opt-out scheme

Avulsion/minor talar fractures

Less than 3 month follow up

Children under the age of 16 years

Data Collection

Data will be collected using a central, electronic database with multiple choice options to gather the following information:

Demographics

Age

Sex

Deprivation status score from postcode (postcode not recorded)

Smoking status

IVDU

Employed

Comorbidities stacked for number of comorbidities – Diabetes, steroids, BMI, osteoporosis

ASA grade

Previous injury to the talus

Previous surgery to the ankle

Fracture factors

Open fracture – Gustilo-Anderson Classification

Associated plastic surgery

Neurovascular injury

Fracture morphology

Hawkins classification (neck)

Talar body - Sneppen

High/low energy – RTC, fall over 3m

Polytrauma – ISS >15 on TARN database

Neck/body/head fracture/lateral process/dislocation without fracture

Comminution medial/comminution lateral/comminution both

Associated ipsilateral fractures – fibula, medial mall, plafond/Pilon, navicular, cuboid

Treatment factors

Initial reduction in ED

Initial open reduction

Cast or ex fix

Treated conservatively or surgically

Arthroscopy assisted

Approaches used - Lateral approach/Medial approach/dual approach/transligamentous/dorsal/Percutaneous

Implants used

Time to reduction hours

Initial temporising procedure performed or straight to definitive surgery

Time to definitive fixation hours

Time of day for initial surgery

Time of day for definitive surgery

Malreduction on Xray or incongruence of ankle or subtalar joint.

Surgeon factors

MTC/TU/DGH

Grade of most senior surgeon

Grade of primary surgeon

Foot and ankle specialist surgeon

Initials of surgeon, how many done by that consultant in study period

Post op

Cast/boot

WB status post op – NWB 0-2, NWB 0-6, NWB >6

Mobilisation of ankle

Complications

Return to theatre

End Outcomes

AVN - collapse on radiograph

AVN sclerosis <1/3, 1-2/3, >2/3

Non-union – **Radiographs** Greater than 6 months, 3 months with no progression, no bridging callus on 2 views. **CT** less than 50% union

Time from date of injury to final xray

OA - Kellgren Lawrence scale for OA of ankle, subtalar, TNJ

Infection

Wound

Metal removal

Further surgery

Revision

CRPS

Return to theatre – removal of metalwork, arthroscopy, infection debridement, other (free text)

Radiographs

Initial AP and lateral radiographs of the talus

Final follow up AP and lateral radiographs of the talus (minimum three months post-injury)

These images are to be shared for every patient within a PowerPoint using the pseudonymised ID for the patient.

Study Design

Retrospective data collection by national multi-centre collaborative using centralised electronic database.

Setting

Multi-centre collaborative. Registered consultants and registrars (maximum 3 doctors per centre for authorship purposes).

Study Timeline

The study will run from 15th February 2026 to 12th June 2026. Data will be collected retrospectively by enrolled centres using their hospital's electronic notes system. Data will be collected using an encrypted, password protected Excel spreadsheet and stored on REDCap in line with DARFI's SOP. We anticipate to finish data collection in June 2026.

Patient Eligibility

Inclusion criteria:

Any talar fracture in adult 16+ in past 13 years with minimum of 3 month follow up sustained between 1st January 2013 and 28th February 2026 (minimum 3 month follow up) will be included. We aim for a study population of over 250 patients nationally.

Exclusion criteria

Patients that are excluded via the National Data opt-out scheme

Avulsion/minor talar fractures

Less than 3 month follow up

Children under the age of 16 years

Patient Identification

Patient identifiable data will be anonymised to a number on the centralised system and the list of these numbers and the patients they refer to will be kept locally.

Data Points

AVN - collapse on radiograph

AVN sclerosis <1/3, 1-2/3, >2/3

Non-union – **Radiographs** Greater than 6 months, 3 months with no progression, no bridging callus on 2 views. **CT** less than 50% union

Time from date of injury to final xray

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Infection

Wound

Metal removal

Further surgery

Revision

CRPS

Return to theatre – removal of metalwork, arthroscopy, infection debridement, other (free text)

Radiographs (initial and final)

Follow Up

Minimum of 3 months follow up for each patient to ensure no late presentations of avascular necrosis.

End of Study

End of study will be defined as data collected by June 2026.

Data Collection and Storage

Centres will enrol to be included in FACT1. Data will be collected by junior/resident doctors under the supervision and guidance of a consultant level orthopaedic surgeons using local hospital systems. **Radiographic data must be collected by a registrar or above (ST3+/SAS/Middle grade/Staff grade/consultants).** Data will be recorded onto a data collection sheet and collated within a centralised electronic system.

Statistical Analysis Plan

The study will use convenience sampling since the national incidence of this injury remains unclear. Statistical analysis will be performed using SPSS 29.0.1 (IBM Corp, USA). Patient characteristics will undergo basic descriptive statistical analyses. The Kolmogorov–Smirnov test was used to test for normality of the data. The Mann–Whitney U test was used when comparing parametric data. Categorical data will be compared using a Chi-squared test. Univariate and multivariate logistic regression analysis were also performed to identify factors predisposing to the development of the relevant outcomes. Any factor which achieved significance on univariate analysis

was included in further multivariate regression analysis. Furthermore, additional AI/ML algorithms (such as, but not limited to: LR, DT, RF, SVM, knn) may be used to explore predictive patterns that may otherwise not be identified using conventional statistical tests. A threshold for p-values less than 0.05 was deemed statistically significant.

Statistical analysis will be performed in association with statisticians from the research department in Liverpool University as well by lead authors.

Local Governance and Ethical Approval

Agreements are in place between Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department and participating organisations, covering all associated DARFI studies.

Ethical approval for DARFI was obtained on 1st February 2024 from the NHS HRA South West - Central Bristol Research Ethics Committee (REC reference: 24/SW/0015, IRAS ID: 331288), covering all associated DARFI approved sub-studies. Permission is given via REC approval to collect this data retrospectively without individual patient consent.

Indemnity for this study is via the NHSLA.

Quality Assurance

Design: Meetings to consider previous literature and study design.

Data completeness: Spreadsheet utilised with drop down menus to ensure comparable data points.

Central monitoring will be conducted to ensure the validity of the uploaded datasets.

Authorship and Mini-teams

All scientific advisory group to be included on authorship.

Two doctors (a senior and a junior PI) will be listed as authors for the first 10 patients contributed by each centre. Thereafter, each centre may add one additional author for every further 10 patients included. For example, a centre contributing 43 patients would be eligible for two authors for the initial 10 patients, plus one additional author for each subsequent block of 10 patients, allowing a maximum of six authors in total.

Patient and Public Involvement

Patient and public involvement was undertaken throughout all stages of the design, development, and delivery of DARFI.

Expected Outputs

As a minimum we aim to produce 1 presentation and 1 publication from this study.

Ideally, we hope to produce 3 publications:

- Risk factors for complications of talar neck fractures
- Risk factors for complications of talar body fractures
- Complications following lateral talar process fractures

Acknowledgements

We thank the **Liverpool University Hospitals NHS Foundation Trust Research & Innovation Department** for kindly hosting DARFI on their REDCap servers.

Website: https://www.liverpoolft.nhs.uk/about-us/research

References

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