ISRCTN94484905 https://doi.org/10.1186/ISRCTN94484905

Safety and performance of OsStic synthetic injectable structural bio adhesive bone void filler in a first in human application to treat tibial fractures

Submission date
26/11/2025

Recruitment status
Not yet recruiting

Registration date
04/12/2025

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study is testing a new material called OsStic, which is designed to fill gaps in broken bones. When someone breaks the top part of their shin bone (called a tibial plateau fracture), surgeons often need to lift the joint surface back into place. This can leave a space in the bone that needs to be filled to help the joint heal properly. Usually, surgeons use bone grafts or other substitutes. This study aims to find out if OsStic is safe to use in this type of surgery and to collect early information on how well it supports healing.

Who can participate?
Adults aged 18 or older who have a closed tibial plateau fracture that needs surgery with a plate and bone filler may be invited to take part. People cannot join if they have an open fracture, are in very poor health, are pregnant or breastfeeding, have certain infections or allergies, or cannot follow the study procedures.

What does the study involve?
Everyone in the study will have the usual operation to fix the fracture with a plate and screws. During surgery, the surgeon will inject OsStic into the gap in the bone. After surgery, participants will receive standard care and physiotherapy. They will attend follow-up visits for about 12 months after surgery (for example at 2 weeks, 6 weeks, 3 months, 6 months and 12 months). At these visits, doctors will check the leg, review any problems, and take X-rays or CT scans to see how the bone is healing. Participants will also complete questionnaires about pain, daily activities and quality of life. At some visits, they may be asked to walk wearing special insoles that measure pressure.

What are the possible benefits and risks of participating?
OsStic is designed to give better support to the joint surface and may help the bone heal well,

but this cannot be guaranteed. The information from this study may help improve treatment for future patients. Risks include a small extra exposure to X-rays and CT scans and the inconvenience of attending follow-up visits.

Where is the study run from?
The study will take place in orthopedic trauma departments in the United Kingdom and will be coordinated by Biomimetic Innovations Ltd, based in Shannon, Ireland.

When is the study starting and how long is it expected to run for?
The study is planned to start recruiting patients in 2026. Recruitment will take about 12 months, and each participant will be followed for around 12 months after surgery. The study is expected to finish by 2028.

Who is funding the study?
The study is funded and sponsored by Biomimetic Innovations Ltd, the manufacturer of OsStic.

Who is the main contact?
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Study information

Scientific Title
A pre-market, single group First in Human (FIH) study to evaluate the safety and performance of a Class III medical device-safety and performance of OsStic synthetic injectable structural bio adhesive bone void filler in a first in human application to treat tibial fractures

Study objectives
To assess the safety of OsStic BVF on pain, functional outcomes in terms of weight-bearing, and overall patient satisfaction.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Blinded (masking used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Tibial plateau fractures

Interventions
This is a prospective, single-arm interventional clinical investigation of the OsStic Synthetic Injectable Structural Bioadhesive Bone Void Filler (OsStic BVF) used during standard surgical fixation of closed tibial plateau fractures. Eligible subjects undergo routine open reduction and

internal fixation (ORIF) with a proximal tibial plate according to local standard of care. After fracture reduction and plate fixation, OsStic BVF is prepared intra-operatively according to the Instructions for Use and injected into the metaphyseal bone void to provide structural support and void filling. The product is supplied as a 10 cc kit and the volume implanted is determined by the surgeon based on the size of the defect. Only surgeons trained in the use of OsStic BVF perform the implantation.

Post-operatively, all subjects receive standard rehabilitation and are followed according to the study schedule with clinical assessment, radiographic/CT imaging and functional evaluation (including gait/load assessment using XSENSOR insoles) to characterize device performance and safety.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
OsStic Synthetic Injectable Structural Bio Adhesive Bone Void Filler (OsStic BVF)

Primary outcome(s)
1. Safety profile of OsStic BVF in tibial plateau fracture surgery measured using the incidence, nature and severity of all adverse events, device complaints and device-related incidents from surgery at (Day 0) to Day 365 (52 weeks)

Key secondary outcome(s))
1. Trend of global pain scores over duration of study to Day 365 (52 W) measured using Numeric Pain Rating Scale for pain while weight bearing: FIX-IT Measure and Numeric Pain Rating Scale for pain at Day 7, Day 14, Day 28, Day 42, Day 84, Day 182 and Day 365

2. Radiological assessment of bone healing measured using CT Scan and AP & LAT x-rays of the knee to determine RRS Score at Day 7, Day 14, Day 28, Day 42, Day 84, Day 182 and Day 365

Completion date
31/05/2028

Eligibility

Key inclusion criteria
1. Patients with traumatic, closed, depression fracture of the tibial plateau (proximal tibia) (limited to AO fracture classification B2 & B3).
2. Candidate patient for bone grafting.
3. Being ambulatory before the injury.
4. Written informed consent.
5. Patients with communicative ability to understand the procedure and participate in the study and comply with the follow up program.
6. Willing and able (in the opinion of the study team) to provide informed consent and participate in all study activities and visits schedule.

Healthy volunteers allowed

Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Open /compound tibial plateau fracture.
2. AO fracture classification Type C.
3. Pathological (Metastatic Tibial Fracture).
4. Multi-segmental nature of this fracture (more than one fracture site within tibia for intervention).
5. Polytrauma (defined as injury severity score of 17 or more).
6. Active systemic infection.
7. Clinically significant or unstable medical or surgical condition that may preclude safe and complete study participation.
8. Exposure to drugs that can affect the bone metabolic state within the past three months.
9. Any pre-existing calcium metabolism disorder (e.g., hypercalcemia).
10. Irreversible coagulopathy or bleeding disorder.
11. Receiving chemotherapy, radiation treatment or immunosuppression drugs.
Patients on long term opioid medication buprenorphine, diamorphine, fentanyl, morphine and oxycodone.
12. History of physical or psychological condition that contraindicates the use of an investigational device or render the patient at high risk from treatment.
13. Pre-existing osteoarthritis.
14. Currently enrolled in any other study which may impact on the results of the present study.
15. If female: pregnant, breastfeeding, or not currently using and not willing to use an effective form of contraception for 12 months post-surgery.

Date of first enrolment
16/02/2026

Date of final enrolment
15/02/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Trauma & Orthopedic Surgery - School of Medicine University of Leeds
Clarendon Wing, Floor D, Leeds General Infirmary
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England
LS1 3EX

Sponsor information

Organisation
Biomimetic Innovations Ltd

Funder(s)

Funder type

Funder Name
Biomimetic Innovations Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			26/11/2025	No	No