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Early versus delayed mobilization after leg fractures with the N-force fixation system

Submission date	Recruitment status	[X] Prospectively registered
17/08/2018	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/09/2018	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/10/2021	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
After having surgery for leg fractures, patients are often advised not to bear weight on this leg for around 6 weeks. This delayed weight bearing allows the fracture time to heal; however, the delay has been associated with other complications, such as osteoporosis and problems with movement. Advances in surgical techniques for fractures, such as one called the N-force fixation system, have been shown to allow patients to bear weight on their limbs sooner, which may avoid these complications. This study aims to look at the differences between the effects of the N-force fixation system on early (after 2 weeks) and late (after 6 weeks) weight bearing after leg fracture surgery.

Who can participate?
Patients aged 18-80 with a proximal fracture of the leg

What does the study involve?
Participants will be randomly assigned to 1 of 2 groups. Both groups will receive fixation surgery for their leg fractures; however, one group will be asked to begin weight-bearing on this leg after 2 weeks (early) and the other will be asked to do so after 6 weeks (delayed). Participants will be asked to complete questionnaires, X-rays and CT scans throughout the study.

What are the possible benefits and risks of participating?
The possible benefit to participants taking part is that early weight-bearing may help to avoid potential complications associated with late weight-bearing. There are no known risks to participants taking part in this study.

Where is the study run from?
Leeds General Infirmary (UK)

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

Who is funding the study?
Zimmer Biomet (USA)

Who is the main contact?
Professor Peter V Giannoudis
Professor and Chairman within Academic Department of Trauma and Orthopaedic Surgery/ Honorary Orthopaedic and Trauma Consultant
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v0.20

Study information

Scientific Title
Tibia plateau pure and split depression fractures (AO 41-B2 and B3) stabilised with N-Force/iN3 bone cement +/- plate augmentation: A prospective single centre feasibility randomised controlled trial comparing early (2 weeks) versus delayed (6 weeks) weight bearing

Acronym
TIB-N-Force Study

Study objectives

Is there a difference between early (2 weeks) and delayed (6 weeks) weight bearing for tibial plateau fractures (Schazker II and III)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Provisional favourable approval from Yorkshire & The Humber - Leeds East Research Ethics Committee, 15/08/2018, 18/YH/0293

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Participants will be randomly allocated using unstratified block randomisation with varying block sizes into 2 arms, with 15-20 patients in each arm. Participants in both groups will receive the same treatment with the N-force system. This is an augmented fixation system, integrating fenestrated screws and a Bone Substitute Material (BSM) called N-Force Blue into a single construct to provide improved metaphyseal void fill and increase structural support of the implant. N-Force Blue is injected directly into the fenestrated screw with the use of a sheath assembly, to help minimise BSM leakage into the soft tissues. This fixation system will be used as a means of surgical fixation for participants' tibial plateau fractures.
After 2 weeks, one group will be asked to begin bearing weight on this leg (2 weeks), whereas the other group will be asked to do so after 6 weeks (delayed).
There will be a 52 week follow-up period, where participants will be assessed at 2, 6, 12, 24 and 52 weeks after surgery.

Intervention Type
Other

Primary outcome measure

1. Quality of life, assessed at the baseline and at week 6, 12, 24 and 52, using:
1.1 12-item Short Form Health Survey (SF-12)
1.2. EuroQol-5D (EQ-5D)
2. Pain whilst weight-bearing, assessed using the Numeric Pain Rating Scale (NPRS) at the baseline and at week 2, 6, 12, 24 and 52
3. Patient mobilisation, assessed using a timed "up-and-go" test (TUG) at weeks 6 and 12

Secondary outcome measures
1. Time to bone healing, assessed using:
1.1. Clinical measures:
1.1.1. Painless full weight bearing
1.1.2. Functional IndeX in Trauma (FIX-IT) score
1.2. Radiological measures - Radiographic Union Scale in Tibial fractures (RUST) scale with a CT scan
2. Proportion of participants healed at 3 and 6 months after surgery
3. Rate of surgical re-intervention at 6 months after surgery
4. Incidence of loss of reduction, secondary collapse or further surgical intervention at the 6 month follow up

Overall study start date
01/03/2017

Completion date
01/04/2020

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Skeletally mature
3. Acute unilateral closed tibia plateau fractures as primary injury
4. Willing and able to provide informed consent and participate in all study activities and visit schedule
5. Ambulatory prior to injury

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Open/compound tibial plateau fracture
2. Fracture type 41 C according to Muller AO classification
3. Multi-segmental fracture (more than one fracture site within tibia)
4. Polytrauma (Injury Severity Score of 17 or more)
5. Prior or concomitant illnesses that may affect healing or outcome
6. Exposure to drugs that can affect the bone metabolic state within the past 3 months
7. Receiving chemotherapy, radiation treatment or immunosuppressant drugs
8. Currently enrolled in any other study that may impact on the results of the present study
9. Resident outside of Leeds
10. Pregnant or breastfeeding
11. If female: not currently using and not willing to use an effective form of contraception for 12 months post-surgery
12. Metal allergy

Date of first enrolment
01/10/2018

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospital NHS Trust
Great George St,
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
university of Leeds

Sponsor details

University of Leeds, Leeds,
Leeds
England
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LS2 9JT

Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Not defined

Funder Name
Zimmer Biomet

Alternative Name(s)
Zimmer Biomet Spine, Zimmer Biomet Biologics

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

Intention to publish date
01/10/2020

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 patient confidentiality.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No