ISRCTN21642113 https://doi.org/10.1186/ISRCTN21642113

Value of body-worn sensors to assess functioning in the follow-up of patients with a hip fracture

Submission date 11/02/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/01/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/05/2025	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoporotic hip fracture treatment remains challenging both due to the increasing age of the population and the high number of complications including death. As a consequence, multiple guidelines have been developed during the last decades to improve the care for geriatric hip fracture patients. Early surgery (surgery within 24 to 48 hours after admission), as well as early mobilization after surgery allowing for full weight bearing, have been proven to be important process indicators. To evaluate the postoperative functionality of geriatric hip fracture patients, both patient-reported, as well as observer-based measurement methods, are used. The aim of this study is to explore the added value of wearable technology for evaluating postoperative functionality through continuous measurement of posture and movement.
There are two primary study aims:
1. To describe patient-reported and observer-based evaluations of functional status during hospitalization for geriatric hip fracture treatment and at follow-up consultations at 6 weeks, 3 months and 6 months after surgery.
2. To evaluate the responsiveness of patient-reported, observer-based and sensor-provided functional assessment methods.

Who can participate?
Patients undergoing surgical repair for proximal femoral fracture, aged 50 years or over, allowed to execute any form of weight bearing

What does the study involve?
Detailed longitudinal follow-up of functioning using patient-reported, sensor-based and observer-based assessments of functioning up to 6 months after surgery.

What are the possible benefits and risks of participating?
Participating will help with the development of feasible, reliable and valid assessments of functioning. This will help with the detection of unfavourable functional outcomes in patients undergoing hip fracture repair. There are no risks associated with this study

Where is the study run from?
1. University Hospitals Leuven (Belgium)
2. KU Leuven (Belgium)

When is the study starting and how long is it expected to run for?
April 2021 to April 2024

Who is funding the study?
1. University Hospitals Leuven (Belgium)
2. KU Leuven (Belgium)

Who is the main contact?
Prof Dr An Sermon (Belgium)
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Contact information

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Public

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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
Added value of a technology-driven assessment of functioning in patients with proximal femoral fracture

Acronym
IMU

Study objectives
1. To describe and compare patient-reported, observed, and technology-measured assessments of physical function (physical activity and functionality) during hospitalization and during follow-up consultations up to 6 months over time in patients with proximal femoral fracture.
2. To compare the responsiveness of patient-reported, observed, and technology-measured assessments of physical functioning (physical activity and functionality) in patients with proximal femoral fracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2021, Ethics Committee Research UZ/KU Leuven (Herestraat 49, 3000 Leuven, Belgium; +32 (0)16 34 86 00; ec@uzleuven.be), ref: S65163

Study design
Single-centre prospective interventional study with retrospective use of Good Clinical Practice data

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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
Surgical repair of proximal femur fractures in patients older than 50 years

Interventions
This study is a monocentric prospective study with an intervention (additional use of one sensor on the chest without health risk to the patient), with retrospective use of Good Clinical Practice (GCP) data collected from 01-01-2021 to 22/04/2021 (physical activity measured by one similar sensor on the leg, the Timed-Up-and-Go test and observation of functioning during the hospitalization period).

After surgery, a sensor will be attached to the affected leg and the chest as soon as possible. This sensor measures physical activity throughout the hospitalization period. These sensors will be re-installed during a consultation at 6 weeks, 3 and 6 months after surgery to measure physical activity for at least 7 days at home. In addition, participants complete several questionnaires: Global Ratings of Perceived Effect, Parker Mobility Score, Pain Assessment, Fall Efficacy Scale and questionnaires on the ease of use of sensor measurements.

In addition, the researchers will perform the following measurements: Harris Hip Score, the Morton Mobility Index (DEMMI) and the timed up-and-go (TUG) test.

Finally, the researchers will also collect general information from the patients' medical records, as well as information about the surgery and rehabilitation.

Intervention Type
Mixed

Primary outcome measure
1. Patient-reported functional status assessed using the Harris Hip Score: Pre-surgery status at day 9 after surgery; week 6, and months 3 and 6 after surgery
2. Observed functional status assessed using DEMMI at Day 9, week 6, and months 3 and 6 after surgery
3. Performance-based functional status assessed using TUG test at Day 9, week 6, and months 3 and 6 after surgery
4. Physical activity assessed using activity sensors during hospitalisation, at least 7 days at home, week 6, and months 3 and 6
5. Health status assessed using Global ratings of perceived effect at week 6, and months 3 and 6

Secondary outcome measures
The following outcomes will be extracted from the patients' medical records or questioned to the patient during hospitalisation and at day 9, week 6, months 3 and 6 after the surgery:
1. Pre-surgery status assessed at day 9 after surgery
2. Demographics and anthropometrics
3. Medical history
4. Time of admission, surgery
5. Surgical procedure, history of hip surgery
6. Time to start mobilization and gait rehabilitation, number and timing of physical therapy sessions
7. Date of admission, medical discharge and discharge (calculation of admission time, admission time until medical discharge)
8. Mental status assessed using a categorical clinician score (electronic patient record), at all time points
9. Comorbidity assessed using the American Society for Anaesthesiologists Physical Status classification
10. Comorbidity assessed using the Charlson Comorbidity Index
11. Medication schedule
12. Fear of falling assessed using the Fall Efficacy Scale
13. Mortality
14. Pain assessed using Numerical Rating Scale
15. Participation assessed using the Parker Mobility Score
16. Feasibility of sensor measurements assessed using Numerical Rating Scale

Overall study start date
09/04/2021

Completion date
26/04/2024

Eligibility

Key inclusion criteria
1. Surgical treatment of proximal femur fracture
2. Age >50 years
3. Immediate weight bearing allowed after surgery

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
65

Key exclusion criteria

1. Revision surgery (affected leg)
2. Pathological fracture
3. Preoperative bedridden, not able to stand up
4. Current COVID-19 infection or other infectious risk requiring isolation
5. Polytrauma/multiple injuries

Date of first enrolment
21/05/2021

Date of final enrolment
21/05/2025

Locations

Countries of recruitment
Belgium

Study participating centre
UZ Leuven
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
https://www.uzleuven.be/en

ROR
https://ror.org/0424bsv16

Funder(s)

Funder type
University/education

Funder Name
KU Leuven

Alternative Name(s)
Katholieke Universiteit Leuven

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

Results and Publications

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

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
Data are available on reasonable request from the corresponding study lead, Prof Dr An Sermon (an.sermon@uzleuven.be), but not publicly, given possible intellectual property affairs related to raw sensor data processing or classification algorithms in this specific population.

IPD sharing plan summary
Available on request