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Orthopaedic surgery in Uganda - Trauma, Infection and Cancer

Submission date
18/01/2025

Recruitment status
No longer recruiting

Registration date
18/02/2025

Overall study status
Completed

Last Edited
11/02/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Orthopaedic trauma, infection and cancer present significant challenges in low- and middle-income countries (LMICs) like Uganda. Trauma-related fractures are a leading cause of disability and economic strain, while pathological fractures from malignancies or infections, such as osteomyelitis, further increase healthcare demands. Sarcomas are a group of often highly malignant cancers, and the patients accumulate in specialised orthopaedic centres. Despite the growing burden, data on treatment outcomes and barriers to orthopaedic care in Uganda remain scarce. This study investigates the management of long bone fractures in Uganda, focusing on traumatic and pathological fractures caused by infections and malignancies. Key objectives include identifying treatment delays, comparing surgical and non-surgical care, and evaluating outcomes and complications. It also explores barriers to care for pathological fractures and current sarcoma management practices. This study will provide critical insights into orthopaedic fracture management in Uganda, identifying gaps and barriers to care. The findings aim to guide clinical interventions, optimize treatments, and improve resource allocation in LMICs.

Who can participate?
Any individual with a traumatic or pathological fracture, or with sarcoma, and who present to Mulago National Referral Hospital or Jinja Regional Referral Hospital in Uganda can participate in the study.

What does the study involve?
The study includes six sub-studies:
1. Traumatic Fractures: Prospective cohort study on treatment practices for major traumatic fractures.
2. Pathological Fractures: Prospective cohort study comparing surgical and non-surgical management and outcomes.
3. Barriers to Care: Qualitative study using interviews to identify delays in care for pathological fractures.
4. Sarcoma Management: Retrospective cohort study on patterns, treatments, and outcomes for sarcoma patients.
5. Vascular injuries in patients with traumatic fractures: Prospective cohort study on vascular injury management in major fractures.

6. Plastic surgery for open fractures: Prospective study on reconstructive surgery outcomes for soft tissue deficits in open fractures.

Studies 1, 4, 5, and 6 involve the use of routine data collection in the hospital and no additional patient contact.

Study 2 includes data collection at the hospital at the time of presentation as well as follow-up after 3 months. This involves an interview, physical examination and direct contact with the research team.

Study 3 is a qualitative study in which persons with pathological fractures can participate. This involves participating in an interview about the condition, the treatment, barriers to care and possible facilitating factors to receive care. The interview will be carried out by members of the research team and it will be audio recorded.

Data collection will evaluate treatment delays, complications, functional outcomes, quality of life, and survival.

What are the possible benefits and risks of participating?
The study does not include any additional investigations or surgical procedures outside of what is the routine at the respective hospital. Therefore, the physical risks introduced by the study are minimal. The potential benefits of participating for the individual are also limited due to the observational nature of this study. The patients with pathological fractures who participate will possibly have access to more detailed information about their condition and thereby, their level of knowledge about their condition could improve as a result of participating in the study.

Where is the study run from?
The study will be run at two public hospitals in Uganda: Mulago National Referral Hospital, and Jinja Regional Referral Hospital.

When is the study starting and how long is it expected to run for?
January 2022 to December 2025. Data collection will run for a total of 6 months during 2025.

Who is funding the study?
The Swedish Research Council

Who is the main contact?
Dr Jenny Löfgren, jenny.lofgren@ki.se

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Orthopaedic trauma, infections and cancer care in Uganda - disease panorama, management and barriers to care

Acronym
OTIC

Study objectives
The project consists of six substudies. The hypotheses of these are outlined below.

Study I: Treatment of Major Traumatic Fractures in Uganda
1. The proportion of patients with major long bone fractures receiving definitive surgical treatment in Uganda is lower compared to high-income countries (HICs).
2. Postoperative complications, such as infections and malalignment, occur at a higher rate in Uganda compared to high-income countries due to resource limitations and delayed interventions.

Study II: Treatment of Pathological Fractures of Long Bones in Uganda
1. The proportion of patients with pathological fractures receiving definitive limb-preserving surgical care is low due to healthcare and financial barriers.
2. Patients who receive delayed surgical treatment for pathological fractures have worse functional outcomes and quality of life compared to those treated promptly.

Study III: Health-Seeking Behavior for Pathological Fractures
1. Barriers such as limited healthcare access, financial constraints, and lack of knowledge delay patients from seeking timely care for pathological fractures.
2. Reducing delays in assessment and treatment can improve outcomes for patients with metastatic bone disease and pathological fractures.

Study IV: Exploring Sarcoma Surgery in Uganda
1. Most patients presenting with sarcomas in Uganda have advanced disease at diagnosis, limiting curative treatment options.
2. Survival outcomes are significantly poorer for patients managed conservatively or with amputation compared to those receiving limb-preserving surgical care.

Study V: The Role of Vascular Surgery in Patients with Major Traumatic Fractures
1. Vascular injuries are underdiagnosed in patients with major traumatic fractures in low-resource settings.
2. Timely detection and appropriate management of vascular injuries significantly reduce rates of amputation and mortality in patients with major traumatic fractures.

Study VI: The Role of Reconstructive Plastic Surgery in Patients with Major Traumatic Fractures
1. The availability and use of reconstructive procedures for wound closure reduce rates of non-union, infections, and amputations in patients with open fractures.
2. Patients undergoing reconstructive procedures experience shorter time to wound closure and better functional outcomes compared to those managed without such procedures.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/01/2025, Uganda Christian University Research Ethics Committee (Plot 67-173, Bishop Tucker Road, Mukono, -, Uganda; +256(0)312 350 885; uncstuganda@gmail.com), ref: UCUREC-2024-1001

Study design
Mixed-methods study carried out in 2 hospitals

Primary study design
Observational

Study type(s)
Other, Quality of life, Treatment

Health condition(s) or problem(s) studied
Traumatic fractures, pathological fractures, sarcoma

Interventions
Patients who present with traumatic fractures, pathological fractures and sarcoma will be included in the study. Information about their condition and management, as well as in-hospital outcomes, will be collected for all. The study does not include running additional tests or investigations, only information that is routinely collected for patients with these conditions will be included. Study participants with pathological fractures will also be followed up after 3 months regarding their level of function and quality of life.

A qualitative study will also be carried out in parallel with the above data collection. In this study, patients with pathological fractures due to infection or metastatic bone disease will be included. They will be interviewed in English or a local language and the interview will be

recorded. The questions are about their condition, how they have sought care and how they received care. It aims to identify barriers to care for this condition and to also identify facilitating factors.

Intervention Type
Other

Primary outcome(s)
Surgical versus non-surgical management of patients with traumatic fractures, pathological fractures and sarcoma, defined as the number of patients undergoing definitive surgery for any of the above conditions divided by the total number of patients with the above conditions during their hospital stay, measured using hospital-based information at one time point

Key secondary outcome(s))
1. Postoperative complications measured using hospital-based information on physical examinations during the time of hospitalisation
2. Functional outcomes and quality of life for patients with pathological fractures measured using physical examination and EuroQol 5D during hospitalisation and at follow-up after 3 months
3. Barriers and facilitating factors to care for persons with pathological fractures measured using qualitative deep interviews during hospitalisation or outpatient visit

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. All patients with traumatic or pathological fractures or sarcoma are eligible for the quantitative part of the study.
2. Only patients with pathological fractures are eligible for the part of the study with 3-month follow-up and the qualitative study

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
All

Lower age limit
0 years

Sex
All

Key exclusion criteria
Unwillingness to participate in the part of the study with pathological fractures

Date of first enrolment
01/02/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Uganda

Study participating centre
Jinja Regional Referral Hospital
Jinja
Uganda
PO Box 43 Jinja

Study participating centre
Mulago National Referral Hospital
Haji Musa Kasule Road
Kampala
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Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Research organisation

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes