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# Quality of life after open fracture of the leg bones

**Submission date**
21/05/2022

**Recruitment status**
No longer recruiting

**Registration date**
06/07/2022

**Overall study status**
Completed

**Last Edited**
04/04/2025

**Condition category**
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Open fractures are severe and life-changing injuries. The management of these patients is complex and best accomplished by multidisciplinary teams. It takes a long time for patients to rehabilitate, and many have permanent loss of function. According to the World Health Organisation, trauma remains relatively neglected in developing countries. Researchers have studied the inequalities of access to treatment from a global perspective by assembling an international collaborative network on lower limb reconstruction (INTELLECT), including hospitals in 16 countries ranging from high to low income. They now plan to take advantage of this network to study the impact of open lower extremity (leg) fractures on quality of life as these data have not been previously described in patients from medium and low-income countries.

Who can participate?
Patients admitted with open lower extremity (leg) fractures to participating hospitals

What does the study involve?
Participants complete questionnaires that measure their quality of life while in the hospital to understand their quality of life before and shortly after an open fracture. This is repeated after 3 and 12 months.

What are the possible benefits and risks of participating?
There are no benefits to the patients that wish to participate in the study. A potential risk is that they may find it distressing to complete a quality of life questionnaire after such an injury.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
June 2020 to March 2024

Who is funding the study?
AO UK&I

Who is the main contact?
Mr Juan Berner
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# Contact information

### Type(s)
Scientific

### Contact name
Mr Juan Berner

### Contact details
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
295778

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IRAS 295778, CPMS 50253

# Study information

### Scientific Title
Quality of life after open extremity trauma (QUINTET): a prospective, multi-centre, international study

### Acronym
QUINTET

### Study objectives
There is an impact on quality of life after an open lower limb fracture.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 19/10/2021, East of England - Cambridge South Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8084, +44 (0)207 104 8104, +44 (0)207 104 8109; cambridgesouth.rec@hra.nhs.uk), ref: 21/EE/0197

### Study design
Observational cohort study

### Primary study design
Observational

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Open lower extremity fractures

### Interventions
Recruited patients complete questionnaires that measure their quality of life while in the hospital to understand their quality of life before and shortly after an open fracture. This is repeated at 3 and 12 months.

### Intervention Type
Other

### Primary outcome(s)
Quality of life measured with the 5-Dimension EuroQol (EQ-5D-3L) and Short Form 12 (SF-12) instruments twice during the acute admission. For the first assessment patients will be asked to appraise their quality of life before their injury and for the second assessment their quality of life at present while an inpatient. This assessment will be repeated at 3 months and 12 months post-injury.

### Key secondary outcome(s))
Clinical outcomes (wound infection, deep infection, non-union, amputation) collected from clinical notes during the period of time that the patient is enrolled in the study (12 months)

### Completion date
31/03/2024

## Eligibility

### Key inclusion criteria
Patients admitted with an open lower limb fracture

### Participant type(s)
Patient

### Healthy volunteers allowed
No

**Age group**
Adult

**Sex**
All

**Total final enrolment**
92

**Key exclusion criteria**
Patients unable to consent

**Date of first enrolment**
01/06/2022

**Date of final enrolment**
31/03/2023

# Locations

**Countries of recruitment**
United Kingdom

England

Austria

Chile

Netherlands

Spain

Sudan

**Study participating centre**
**Hospital del Trabajador de Santiago**
Ramon Carnicer 19
Santiago
Chile
00000

**Study participating centre**
**Hospital Universitario de Canarias**
Carretera Ofre S/N

Santa Cruz de Tenerife
Spain
38320

**Study participating centre**
**St Mary's Hospital**
Praed Street
London
United Kingdom
W2 1NY

**Study participating centre**
**St Georges Hospital**
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

**Study participating centre**
**University Hospital (coventry)**
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

**Study participating centre**
**The Royal Victoria Infirmary**
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

**Study participating centre**
**Hull Royal Infirmary**
Anlaby Road
Hull
United Kingdom
HU3 2JZ

# Sponsor information

### Organisation
University of Oxford

### ROR
https://ror.org/052gg0110

# Funder(s)

### Funder type
Charity

### Funder Name
AO UK&I

# Results and Publications

### Individual participant data (IPD) sharing plan
Participant level data will not be made freely available as per the researchers' agreement with the ethics committee that reviewed this study.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/12/2024 | 04/04/2025 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol file | version 1.2 | 10/11/2022 | 06/03/2023 | No | No |