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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
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Additional identifiers

Integrated Research Application System (IRAS)
295778

Central Portfolio Management System (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

Primary study design
Observational

Study design
Observational cohort study

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