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The impact of COVID-19 pandemic on the assessment, management and outcomes for patients with common upper limb fractures

Submission date
19/03/2021

Recruitment status
No longer recruiting

Registration date
26/04/2021

Overall study status
Completed

Last Edited
15/12/2022

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
The study aim is to investigate the impact of COVID-19 pandemic on wrist (distal radius) and shoulder (proximal humerus) fracture management within the UK, and investigate the impact on patient recovery.

Who can participate?
Patients who have previously presented pre-pandemic (1 December 2019 to 14 March 2020) and during the prevalent phase of UK COVID-19 pandemic (15 March to 30 June 2020) to orthopaedic services with fractures of the wrist and shoulder.

What does the study involve?
For patients who consent, we will collect baseline demographic data, underlying health conditions, fracture details, and preferred vs provided treatment. Follow up patient questionnaires at 12 and 24 months post injury will include questionnaires to assess outcomes. We will also collect data from hospitals on the details of treatment received; re-admissions; complications; secondary interventions; and mortality.

What are the possible benefits and risks of participating?
The study will improve our understanding of the impact of the Covid-19 pandemic on upper limb fracture care. The results of this study are likely to generally help inform other research studies that have been suspended due to Covid-19, about the potential impact of the pandemic on participants of those studies and the impact on patient outcomes due to changes in treatment pathways during the pandemic. It may also help us design appropriate care pathways for patients with upper limb fractures if services are affected in the future as a result of a pandemic. There are no identified disadvantages or risks from taking part in this research study due to the observational nature.

Where is the study run from?
The James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2021 to May 2023

Who is funding the study?
AO UK & I (UK)

Who is the main contact?
Dr Lucksy Kottam, lucksy.kottam@nhs.net
Prof. Amar Rangan, amar.rangan@york.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
292033

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48040, IRAS 292033

Study information

Scientific Title
The impact of COVID-19 pandemic on the assessment, management and outcomes for patients with common upper limb fractures in the UK: a multi-centre observational cohort study. [FAMOUS-C19 (Fracture Assessment, Management and Outcomes in Upper limb Study during Covid-19)]

Acronym
FAMOUS-C19

Study objectives
The study aim is to investigate the impact of COVID-19 pandemic on wrist (distal radius) and shoulder (proximal humerus) fracture management within the UK, and to quantify any impact on patient outcomes.

This study has been designed to capture key information on changes in management of adults with common upper extremity fractures within orthopaedic trauma services in the UK during the COVID-19 pandemic. Patients with these fractures and their outcomes will be assessed to improve our understanding of the impact of the COVID-19 pandemic on fracture care. The results of this study are also likely to more generally help inform other clinical trials that have been suspended due to COVID-19, about the potential impact of the pandemic on trial participants. Our established and effective clinical recruiting networks for trauma and orthopaedic trials, including the trainee research collaborative CORNET (Collaborative Orthopaedic Research Network) will help deliver the project within the specified timescale.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2021 East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048276; derby.rec@hra.nhs.uk), ref: 21/EM/0014

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
The impact of COVID-19 pandemic on patients with wrist or shoulder fracture

Interventions
This is a UK-wide multi-centre observational study, including remote follow up with patient questionnaires. Up to 500 adult patients who have previously presented pre-pandemic (1 December 2019 to 14 March 2020) and during the prevalent phase of UK COVID-19 pandemic (15 March to 30 June 2020) to orthopaedic services with fractures of the wrist and shoulder will be approached to consider participating in the study.

For patients who consent, we will collect baseline demographic data, underlying health conditions, fracture details, and preferred vs provided treatment. Follow up patient questionnaires at 12 and 24 months post injury will include validated items to assess outcomes, and will include: EQ-5D-5L; other fracture specific measures (OSS, PRWE); COVID-19 status (suspected/confirmed); experiences in accessing health care; and satisfaction with treatment. We will also collect data from hospitals on the details of treatment received; re-admissions; complications; secondary interventions; and mortality.

Intervention Type
Other

Primary outcome measure
Patient-reported outcomes in the management of upper extremity fractures:
1. OSS for Proximal Humeral Fractures at baseline and 24 months
2. PRWE for Wrist fractures at baseline and 24 months

Secondary outcome measures
Collected at baseline:
1. Demographic data, underlying health conditions, fracture details, preferred vs provided treatment details.
Collected at 12 and 24 months:
2. Quality of life (EQ-5D-5L)
3. Fracture specific measures (OSS/PRWE)
4. COVID-19 status (suspected/confirmed) measured using ‘Non validated Patient Reported Outcome Questionnaire’

5. Experiences in accessing health care measured using ‘Numeric Rating Scale’
6. Satisfaction with treatment measured using – ‘Numeric Rating Scale’
7. Loss of productivity (i.e. days off work; change in work status) measured using ‘Non validated Patient Reported Outcome Questionnaire’
Collected at hospital follow-up 24 months using patient records:
8. Treatment received
9. Re-admissions
10. Complications
11. Secondary interventions
12. Mortality

Overall study start date
07/01/2021

Completion date
02/05/2023

Eligibility

Key inclusion criteria
Adult patients who have presented to the orthopaedic trauma service within participating NHS hospitals with radiologically confirmed fractures of the proximal humerus or distal radius between 1 December 2019 to 14 March 2020 (Pre-pandemic phase) and between 15 March 2020 and 30 June 2020 (Pandemic phase).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria
Patients who lack the mental capacity to understand and complete the study procedures and pathological (other than osteoporotic/fragility related) fractures.

Date of first enrolment
01/04/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment

England

Scotland

United Kingdom

United States of America

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Marton Road
Middlesbrough
Cleveland
United Kingdom
TS4 3BW

Study participating centre
University Hospital of North Tees
North Tees and Hartlepool NHS Foundation Trust
Hardwick
Stockton on Tees
United Kingdom
TS19 8PE

Study participating centre
Addenbrooke's Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Manchester Royal Infirmary
Central Manchester University Hospitals NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Sussex County Hospital
Brighton & Sussex University Hospitals
Kemptown
Brighton
United Kingdom
BN2 1ES

Study participating centre
Nottingham City Hospital
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
NG5 1PB

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel Road
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Salford Royal Hospital
Salford Royal NHS foundation trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Victoria Hospital
Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre

Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Tameside General Hospital
Tameside Hospital Integrated Care NHS Foundation Trust
Fountain Street
Ashton-under-Lyne
United Kingdom
OL6 9RW

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
United Kingdom
GU16 7UJ

Study participating centre
University Hospital North Durham
County Durham and Darlington NHS foundation trust
North road
Durham
United Kingdom
DH1 5TW

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals
Kadoorie Centre
Level 3
Headley Way
Oxford
United Kingdom
OX3 9DU

Study participating centre
Aintree University Hospital
Liverpool University Hospitals NHS Foundation Trust
Lower Ln
Liverpool
United Kingdom
L9 7AL

Study participating centre
Chesterfield Royal Hospital
Calow
Top Road
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Princess Alexandra Hospital
The Princess Alexandra Hospital NHS Trust
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Leicester
United Kingdom
LE1 5WW

Study participating centre
North Manchester General Hospital
Pennine Acute Hospitals NHS trust
Delaunays Road
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre

Norfolk & Norwich University Hospital
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
University Hospital Coventry
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS Foundation Trust
North Shields
United States of America
NE29 8NH

Study participating centre
Royal Victoria Infirmary
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Study participating centre
The Queen Elizabeth Hospital
The Queen Elizabeth Hospital NHS Foundation Trust
Gayton Road,
King’s Lynn
United Kingdom
PE30 4ET

Study participating centre
Ipswich Hospital
East Suffolk and North Essex NHS Foundation Trust

Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Broomfield Hospital
Mid and South Essex NHS Foundation Trust
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Royal Blackburn Hospital
East Lancashire Teaching Hospitals NHS Trust
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Glasgow Royal Infirmary
NHS Greater Glasgow & Clyde
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Aberdeen Royal Infirmary
NHS Grampian
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation

South Tees Hospitals NHS Foundation Trust

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James Cook University Hospital
Marton Road
Middlesbrough
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TS4 3BW
+44 (0)1642 854089
joe.millar@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://southtees.nhs.uk/

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Charity

Funder Name
AO UK & I

Results and Publications

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

Intention to publish date
02/05/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Anonymised aggregate data will be held securely at South Tees Hospitals NHS Foundation Trust and can be made available on appropriate request with clearly stated purpose. They could write to Prof Amar Rangan via email amar.rangan@york.ac.uk with the request. Data will be available for 5 years from study completion.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.0	15/01/2020	26/04/2021	No	Yes
HRA research summary			28/06/2023	No	No