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The Operative Rib Fixation (ORiF) study

Submission date
29/05/2019

Recruitment status
No longer recruiting

Registration date
30/05/2019

Overall study status
Completed

Last Edited
27/02/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Rib fractures are a common injury. They usually occur as a result of a serious injury, such as those suffered in a road traffic accident or falling from a height. They can also occur in less traumatic accidents, often in elderly people who have fragile bones. Rib fractures are painful and can cause problems with breathing. Lung tissue sits just underneath the ribs and when a fracture occurs, the lungs are also often injured. As a result, rib fractures can lead to problems such as pneumonia, pulmonary effusions (the build-up of fluid in the lungs due to swelling), and some patients can even die as a result of the injury. Most rib fractures are treated without the need for an operation. Doctors use supportive treatments such as pain relief and physiotherapy to help patients recover. Fractures in other bones are usually fixed with an operation that secures the broken bones using metal plates and screws. Recently surgeons have found that some rib fractures can also be fixed in this way. They have also found patients are recovering better with an improvement to their quality of life. However, surgery always carries some risk, especially in patients who have had major injuries. It is not known whether surgical treatment, and its risks, is better than the current non-operative/supportive treatments. The aim of this study is to compare rib fixation with plates and screws to the supportive treatments currently available in the NHS.

Who can participate?
Patients with three or more rib fractures suitable for surgical repair and one or more of the following: clinical flail chest, breathing difficulty requiring support, and uncontrollable pain using standard modalities

What does the study involve?
Participants are randomly allocated to receive either supportive treatments, as is the standard care, or to also undergo an operation to stabilise their rib fractures. Patient outcomes (survival after the injury and quality of life, among other things) and also the cost of treatment to the NHS are measured up until study completion at 12 months. Most of the information is routinely collected in hospitals through an existing system, but some other details are collected directly from patients by specialist research nurses at routine visits to the clinic.

What are the possible benefits and risks of participating?
Both supportive management and operative rib fixation are already routinely carried out in the NHS. However, surgery always carries some risk, especially in patients who have experienced

major injuries. Although there is some evidence to suggest a reduced length of hospital stay and improved quality of life in some patients who undergo operative rib fixation, a benefit cannot be guaranteed to those who take part in this study. The results from the study are likely to benefit future patients with multiple rib fractures, as it is not known whether the surgery, and its risks, are better than the current non-operative, supportive treatments.

Where is the study run from?
15 trauma centres across the UK

When is the study starting and how long is it expected to run for?
June 2018 to December 2024

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
1. Prof Benjamin Ollivere, Benjamin.Ollivere@nottingham.ac.uk
2. Mr Nicholas Beale, orif@ndorms.ox.ac.uk

Study website
https://orif.octru.ox.ac.uk/

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18OR001, HTA 16/61/10

Study information

Scientific Title
A multicentre randomised controlled trial assessing the mortality, quality of life, and cost-effectiveness of operative rib fixation plus supportive management versus supportive management alone for patients with multiple rib fractures

Acronym
ORiF

Study objectives
Operative rib fixation with supportive management is better than supportive management alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/01/2019, South Central – Berkshire Research Ethics Committee (Easthampstead Baptist Church, South Hill Road, Bracknell, RG12 7NS; Tel: +44 (0)0207 104 8360, +44 (0) 2071048046; Email: nrescommittee.southcentral-berkshire@nhs.net), REC ref: 18/SC/0666

Study design
Pragmatic interventional multi-centre two-arm parallel group randomized controlled trial nested within a population registry

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Available on request

Health condition(s) or problem(s) studied
Rib fractures

Interventions
1:1 randomisation where patients will receive either:
1. Operative rib fixation plus supportive management (intervention)
2. Supportive management alone (control)
Minimisation factors: age; polytrauma; mechanical ventilation and study site

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 11/12/2023:

All-cause mortality at 12 months

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Previous primary outcome measure:

1. All-cause mortality at 12 months
2. Quality of life measured using the EQ-5D-5L questionnaire at baseline, 30 days, 3 months, 6 months and 12 months

Secondary outcome measures
Current secondary outcome measures as of 17/03/2023:
1. Quality of life measured using the EQ-5D-5L questionnaire at baseline, 30 days, 3 months, 6 months and 12 months
2. Patient-reported pain and function measured using the pain Visual Analogue Scale (VAS) and function-related patient questionnaire at 3 months, 6 months and 12 months
3. Need for further intervention assessed using patient medical records and Trauma Audit and Research Network (TARN) data, specifically: operative and supportive management details (until discharge), complications (over 12 months), further intervention (over 12 months), ventilator days (until discharge), CT imaging (at baseline) and x-ray imaging (at 6 – 8 weeks post-discharge

for the operative group only)
4. Length of stay (LOS) until discharge, assessed using patient medical records and Trauma Audit & Research Network (TARN) data
5. Cost-effectiveness measured using a Health Resource Use questionnaire at 6 months and 12 months
6. Generalisability of the findings from the randomised trial against the population registry data over 12 months, using a recent statistical approach, using TARN data for both randomised and non-randomised patients

Previous secondary outcome measures:
1. Patient-reported pain and function measured using the pain Visual Analogue Scale (VAS) and function-related patient questionnaire at 3 months, 6 months and 12 months
2. Need for further intervention assessed using patient medical records and Trauma Audit and Research Network (TARN) data, specifically: operative and supportive management details (until discharge), complications (over 12 months), further intervention (over 12 months), ventilator days (until discharge), CT imaging (at baseline) and x-ray imaging (at 6 – 8 weeks post-discharge for the operative group only)
3. Length of stay (LOS) until discharge, assessed using patient medical records and Trauma Audit & Research Network (TARN) data
4. Cost-effectiveness measured using a Health Resource Use questionnaire at 6 months and 12 months
5. Generalisability of the findings from the randomised trial against the population registry data over 12 months, using a recent statistical approach, using TARN data for both randomised and non-randomised patients

Overall study start date
01/06/2018

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Patients who present with multiple (three or more) rib fractures suitable for surgical repair and one or more of the following:
1. Clinical flail chest
2. Respiratory difficulty requiring respiratory support
3. Uncontrollable pain using standard modalities

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
524

Total final enrolment
467

Key exclusion criteria
1. Aged under 16 years
2. Thoracic injury requiring emergent operative or interventional radiology
3. Cannot be operated on within 72 hours as deemed unfit for surgery

Added 06/10/2021:
4. Unwilling or unable to comply with protocol follow up requirements
5. Any other significant disease or condition which, in the opinion of the local research team, may influence the results of the trial or the patient's ability to participate in the trial

Date of first enrolment
01/04/2019

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Marton Road
Middlesbrough

United Kingdom
TS4 3BW

Study participating centre
Morriston Hospital
Swansea Bay University Health Board
Morriston
Swansea
United Kingdom
SA6 6NL

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
Headley Way
Oxford
United Kingdom
OX3 9DU

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

Study participating centre
Queen Elizabeth Hospital
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Birmingham
United Kingdom
B15 2GW

Study participating centre
Derriford Hospital
Derriford Road
Derriford

Plymouth
United Kingdom
PL6 8DH

Study participating centre
Kings College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

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

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

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

Study participating centre
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
St. Mary's Hospital
Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Manchester Royal Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Aberdeen Royal Infirmary
Grampian Health Board
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Research & Innovation
Queen’s Medical Centre
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+44 (0)1159 249924
ResearchSponsor@nuh.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings will be published in a high impact peer-reviewed journal and will be disseminated across the surgical and anaesthetic communities, the wider medical community and NICE. Study papers will be published in high impact factor journals and will be made available under open access so that high visibility of the work will be maintained as per the NIHR policy.

Intention to publish date
01/10/2025

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 17/03/2023:
On completion of the study, and with appropriate participant consent, fully anonymised data may be shared with other organisations at the behest of the funder. All requests for the use of the data from the ORiF study will be approved by the CI, TMG and where necessary the TSC. A data request form should be completed detailing the decision as to whether the request is accepted. In cases where individual site data is requested, only summary data would be provided with caveats for dissemination, to emphasise that trial data should be interpreted as a whole.

Previous IPD sharing statement:
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 6.0	10/07/2023	16/12/2024	No	No
Statistical Analysis Plan	version 1.0	20/12/2024	27/02/2025	No	No