

# The Operative Rib Fixation (ORiF) study

<b>Submission date</b> 29/05/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/05/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/02/2025	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

## Contact information

### Type(s)

Scientific

### Contact name

Prof Benjamin Ollivere

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### Type(s)

Public

### Contact name

Mr Nicholas Beale

### ORCID ID

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orif@ndorms.ox.ac.uk

## **Additional identifiers**

**Protocol serial number**  
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

### **Study type(s)**

Quality of life

### **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(s)**

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

## **Key secondary outcome(s)**

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
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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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Sex**

All

**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

United Kingdom

England

Scotland

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

#### Morrison Hospital

Swansea Bay University Health Board  
Morrison  
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

**ROR**  
<https://ror.org/05y3qh794>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 6.0	10/07/2023	16/12/2024	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	20/12/2024	27/02/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes