

Scaphoid Waist Internal Fixation for Fractures Trial: A trial evaluating cast versus surgical fixation for fractures of the scaphoid waist in adults

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| Submission date 07/02/2013 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 13/02/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 19/08/2021 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

This study seeks to answer the question of whether adults with a fracture of the scaphoid waist should receive plaster cast treatment or surgical fixation? Fracture of the scaphoid bone (one of eight small bones in the wrist) is common in young active people, and results from a fall on the hand or sudden forced twist of the wrist. The usual standard treatment is to rest the wrist in a plaster cast for 6 to 10 weeks and allow the broken scaphoid bone to heal. However, in the last few years, another way of holding all of these fractures still while they heal has been to operate early on the wrist and to fix the broken bone with a special screw. We do not know which treatment is better without the evidence from a sufficiently large and detailed study.

Who can participate?

Men and women, aged 16 or over, who have fractures of the scaphoid waist and present to the hospital fracture clinic within 3 weeks of their injury, provided no exclusion criteria apply.

What does the study involve?

Eligible participants who consent to take part will be assessed at baseline using questionnaires, grip and strength measurements for their hand and wrist function and X-rays and CT scans. Patients will then be allocated into one of two groups: the surgical group or plaster cast group. This is done through a computerised process called randomisation, which means participants are allocated to groups purely by chance, in a similar way to using the toss of a coin. Patients in the surgery group will receive an operation, carried out by an orthopaedic surgeon experienced in treating wrist fractures. The surgeon will then advise about the best care of the wrist after surgery, including the use of hand and wrist exercises.

Patients in the plaster cast treatment group will have the plaster cast applied, which will usually remain in place for 6 to 10 weeks, depending on how well the bone is healing when it is examined. Once the cast is removed, the surgeon will advise about exercises for the wrist. If, upon examination at 6 or 12 weeks, the surgeon does not think that the bone is healing sufficiently in a cast, then further X-rays and/or a CT scan may be routinely requested to help

them decide about the need for an operation to fix the bone in place. This can happen to around 1 in 10 patients and is normal practice for when the bone does not heal when treated in a plaster cast. To monitor their progress we will ask patients to attend follow-up appointments at the hospital and/or to complete a short questionnaire. These will take place at 6, 12, 26 and 52 weeks. To assess any longer-term effects, such as arthritis, we will ask patients to attend an additional follow-up appointment at 5 years. Some patients will also be asked whether they would like to take part in an interview to explore and improve understanding of patients attitudes towards and experiences of the treatments that are being compared in this study. This will also help us to learn about patients experiences of taking part in a research study.

What are the possible benefits and risks of participating?

While the selection of treatment (surgery or plaster cast) is left to chance, patients will receive the same standard of care as they would normally. The surgeon and other people providing care are experienced in the treatments provided. There are no new treatments being tested in this study. There are risks associated with having any operation, such as infection, bleeding and very rare damage to the nerves, however, it is possible that this may restore hand function earlier and avoid the need to have the wrist held in a plaster cast for 6 to 10 weeks. There are also possible long term effects if the fracture does not join. If left untreated, this often leads to arthritis within 5 years. One in ten fractures treated in a plaster cast do not heal and can lead to delayed surgery. The plaster cast treatment, however, can prevent the need for the majority of patients to have an operation and the extra risks involved. Because we do not know what treatment is best, patients may not benefit from taking part. If, however, enough people take part in this study, the information we get should help ensure that people with these fractures have the best treatment in the future.

Where is the study from?

We will recruit patients from hospitals across the UK.

When is the study starting and how long is it expected to run for?

April 2013 to April 2022

Who is funding the study?

The NIHR Health Technology Assessment Programme (HTA), UK

Who is the main contact?

Prof. Joe Dias

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 11/36/37

Study information

Scientific Title

A multi-centre randomised controlled trial evaluating the effectiveness and cost-effectiveness of cast treatment versus surgical fixation for fractures of the scaphoid waist in adults

Acronym

SWIFFT

Study objectives

To assess the effectiveness and cost-effectiveness of surgical fixation versus plaster cast immobilisation for fractures of the scaphoid waist in adults.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/113637>

Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/81157/PRO-11-36-37.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial and economic evaluation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Musculoskeletal trauma of the hand and wrist

Interventions

Participants will be randomised to one of two basic treatment interventions:

1. Surgery using a headless screw
2. Plaster cast immobilisation

Intervention Type

Procedure/Surgery

Primary outcome measure

The Patient Rated Wrist Evaluation (PRWE) (15 item condition-specific questionnaire providing a total score based on the patient's subjective assessment of wrist pain and disability in activities of daily living), assessed at 52 weeks

Secondary outcome measures

1. The PRWE at 6, 12 and 26 weeks and at 5 years
2. The 12-item short form health survey (SF-12) and Euroqol (EQ-5D) for general health status data (at 6, 12, 26, 52 weeks and 5 years)
3. Bone union, determined by CT scan and radiographs at 52 weeks and 5 years
4. Range of wrist movement (measured using goniometer at 6, 12, 52 weeks and 5 years).
5. Grip strength (measured using a calibrated Jamar dynamometer at 6, 12, 52 weeks and 5 years)
6. Complications, including surgical complications (e.g. wound infection) at 6, 12, 52 weeks
7. Early medical complications, i.e. chest infection, confirmed myocardial infarction or stroke, treated deep vein thrombosis and pulmonary embolism.
8. Subsequent referral for operation or substantive treatment. Duration of follow-up: 5 years
9. Data for economic evaluation: NHS and societal costs

Overall study start date

01/04/2013

Completion date

31/03/2022

Eligibility

Key inclusion criteria

1. Adults (male and female), aged 16 years old or above
2. Presenting to the trauma centre within 2 weeks of their injury
3. Radiologically confirmed bicortical fracture of the scaphoid waist

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

438

Total final enrolment

439

Key exclusion criteria

1. Fractures greater than 2mm displaced
2. Fractures in the proximal pole of the scaphoid (proximal 20%)
3. Trans-scaphoid perilunate dislocation
4. Multiple injuries in the same limb
5. Previous injury or disease in the same wrist
6. Patients with cognitive impairment
7. Patients not resident in the trauma centre catchment area
8. Any other reason to exclude the patient (please give reasons)

Date of first enrolment

01/04/2013

Date of final enrolment

31/07/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Leicester General Hospital

Leicester

United Kingdom

LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type

Hospital/treatment centre

Website

<http://www.leicestershospitals.nhs.uk/>

ROR

<https://ror.org/02fha3693>

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**

Not provided at time of registration

Intention to publish date

31/12/2019

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

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------------|--------------------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 04/06/2016 | | Yes | No |
| Results article | results | 01/08/2020 | 12/08/2020 | Yes | No |
| Funder report results | | 01/10/2020 | 19/08/2021 | No | No |
| Results article | cost-effectiveness | 01/07/2021 | 19/08/2021 | Yes | No |