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

Submission date
07/02/2013

Recruitment status
No longer recruiting

Registration date
13/02/2013

Overall study status
Completed

Last Edited
19/08/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
jd96@leicester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Joe Dias

Contact details
Clinical Sciences Unit, Off Ward 11
Leicester General Hospital
Gwendolen Road
Leicester

United Kingdom
LE5 4PW
+44 (0)116 258 4702
jd96@leicester.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (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, 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
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?
Results article	results	01/08/2020	12/08/2020	Yes	No
Results article	cost-effectiveness	01/07/2021	19/08/2021	Yes	No
Protocol article	protocol	04/06/2016		Yes	No
Funder report results		01/10/2020	19/08/2021	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes