

Intramedullary screws versus Kirschner wires (pins) for finger fractures

Submission date 23/11/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/11/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/12/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

When someone breaks a finger, surgery is sometimes needed to make sure the bones heal properly. There are different ways to fix broken bones in the fingers, such as using plates, pins, or screws. Each method has pros and cons. Pins are easy to insert but require the finger to be kept still for about four weeks, which can delay recovery. Screws are a newer option that may allow people to move their fingers sooner and return to work faster. This study aims to compare pins and screws to see which method helps patients recover better in terms of movement, grip strength, and overall satisfaction.

Who can participate?

Adults aged 18 or older who need surgery for a broken finger bone (proximal or middle phalanx) at our hospital can take part, as long as the break can be fixed without opening the joint and they can give consent and complete questionnaires in English.

What does the study involve?

Participants will be randomly assigned to have their broken finger fixed with either pins or screws. Both methods are standard treatments. After surgery, everyone will have a splint and start gentle finger exercises with a hand therapist after one week. Follow-up visits will happen at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 6 months, and 1 year, including X-rays and checks by the surgical team and therapist.

What are the possible benefits and risks of participating?

The benefit is that you may receive a treatment that helps you recover faster and with better finger movement. The risks are similar to any finger surgery, such as infection, stiffness, or scarring. Both treatments are already widely used in practice.

Where is the study run from?

McMaster University in Canada (UK)

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

The study will start in December 2025 and is expected to run until June 2029.

Who is funding the study?

The study is funded by the PSI Foundation and Wrist Evaluation Canada.

Who is the main contact?

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Study information

Scientific Title

Intramedullary screw versus Kirschner wire fixation of extraarticular proximal and middle phalanx fractures: a multicenter randomized controlled trial

Acronym

HANDFIX

Study objectives

The primary objective of this study is to compare two closed reduction techniques, i.e. intramedullary screw fixation to Kirschner wire fixation, in adult patients with extraarticular proximal or middle phalanx fractures.

Ethics approval required

Ethics approval required

Ethics approval(s)

submitted 23/11/2025, Hamilton Integrated Research Ethics Board (237 Barton St E, Hamilton, L8L 2X2, Canada; +1 905 521-2100; belle@hhsc.ca), ref: 19626

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Middle or proximal phalanx fractures

Interventions

The treatment arms for this study will be operative fixation of proximal or middle phalanx fractures using IM screws versus K-wires.

For IM screw fixation, the fracture will first be reduced by the surgeon using a closed technique. A small incision will then be made at the head or base of the proximal or middle phalanx. Skin and extensor mechanism will be retracted to expose the planned screw entry side. One or two IM screws of appropriate width and length based on the patient's bony morphology and fracture pattern will then be placed in the phalanx to hold the reduction. Fluoroscopy will be used during the process. The patient will be placed in a plaster splint.

For K-wire fixation, the fracture will first be reduced by the surgeon using a closed technique. One or multiple K-wires will be placed to hold the fracture reduction. Fluoroscopy will be used during the process. K-wires will be cut outside the skin and a plaster splint will be applied. The K-wires will be removed at the 4-week visit unless a post-operative infection necessitates earlier removal or clinical signs of delayed fracture healing necessitates later removal.¹⁴

For both groups, protected early range of motion will be initiated by a licensed hand therapist 1 week post-operatively and patients will be offered a thermoplastic splint during their 1-week hand therapy visit. Hand therapy and splinting will be progressed as per the hand therapists' and

the surgeons' discretions based on clinical examination. Patient will be seen at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 6 months, and 1 year post-surgery by the surgical team and hand therapy. X-rays will be performed preoperatively and at 4 weeks and 12 weeks post-surgery as per standard of care. Surgical details will also be recorded.

All aspects of care provided to participants as described above is the current standard of practice except for randomization to intervention.

Randomization will be performed in a 1:1 ratio using randomization in blocks of 4. Randomization will be performed using Research Randomizer (Version 4.0) and the sequence will be uploaded to the REDCap randomization module. The allocation sequence will be generated by a research member who is not involved with patient recruitment or clinical patient care, and allocation will occur after initial patient consultation and recruitment preoperatively.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Quality of life measured using Disabilities of the Arm, Shoulder, and Hand at 12 weeks

Key secondary outcome(s)

1. Quality of life measured using Disabilities of the Arm, Shoulder, and Hand at baseline, 4 weeks, 6 months, 1 year

2. Quality of Life measured using EQ-5D-5L at baseline, 4 weeks, 12 weeks, 6 months, 1 year

3. Pain measured using Visual Analogue Scale at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 6 months, 1 year

4. Range of motion measured using Goniometer at 4 weeks, 8 weeks, 12 weeks, 6 months, 1 year

5. Grip strength measured using Dynamometer at 8 weeks, 12 weeks, 6 months, 1 year

6. Time from surgery to return to work measured using patient records at 1 year

7. Radiological details measured using X-ray at 4 weeks, 12 weeks

8. Complications/adverse events measured using Clinical assessment at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 6 months, 1 year

Completion date

30/06/2029

Eligibility

Key inclusion criteria

1. Adult patients ≥ 18 years old

2. Scheduled for operative management of extraarticular proximal or middle closed phalanx fracture(s) at our tertiary hospital

3. Feasible to perform closed reduction

4. Able to provide informed consent and complete health-related quality of life (HRQoL) questionnaires in English

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Other fractures that cannot be managed with IM screws or K-wires
2. Fractures affecting both hands
3. Other significant injury to the contralateral upper extremity
4. Other intraarticular fractures
5. Significant concomitant hand trauma
6. Cannot commit to 3 month follow up at our institution

Date of first enrolment

01/01/2026

Date of final enrolment

30/06/2028

Locations**Countries of recruitment**

Canada

Sponsor information**Organisation**

McMaster University

ROR

<https://ror.org/02fa3aq29>

Funder(s)

Funder type

Funder Name
PSI Foundation

Funder Name
Wrist Evaluation Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		30/10/2025	24/11/2025	No	No