

A proposective randomised clinical trial comparing the outcomes of external fixation and a new concept of percutaneous k-wiring

Submission date 12/09/2003	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 27/10/2009	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0192107595

Study information

Scientific Title

Study objectives

Currently, we feel that the methods used to perform k-wiring are incorrect. We wish to propose a new way to perform percutaneous k-wiring to improve the outcomes of this procedure in intra fractures of the distal radius. We also postulate that the outcomes from this procedure are significantly better with lesser complications than external fixation. This surgical procedure has significantly lower cost implications in the overall treatment of the patient with distal radial fractures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Percutaneous k-wiring

Interventions

Laboratory study:

A: Percutaneous k-wiring

B: External fixation

The trial was registered when the trialist was at Queens Medical Centre Nottingham but the trial did not start.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

1. Radiological outcome: X-rays at varying timepoints until union of the fracture. Various measures will be performed on these X-rays to ascertain the anatomical end point.
2. Clinical outcome: A detailed clinical examination at varying time points, measuring the objective end point with respect to range of movement, grip strength and complications will be recorded. A questionnaire to measure the subjective end point will be completed by the patient.

Key secondary outcome(s)**Completion date**

01/12/2003

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility**Key inclusion criteria**

Total number of subjects = 100.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

13/12/2001

Date of final enrolment

01/12/2003

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

East Surrey Hospital

Redhill

United Kingdom

RH1 5RH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Queens Medical Centre University Hospital NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration