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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 distral 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 distral radial fractures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

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