

Comparison of the Teno Fix Tendon Repair System and a standard suture repair in Zone II flexor tendon lacerations of the hand.

Submission date 30/09/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 26/04/2011	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
N0013145917

Study information

Scientific Title

Study objectives

Is there a reduced rupture rate and improved outcome using the Teno Fix Tendon Repair System in comparison to a standard suture repair in zone II flexor tendon lacerations in the hand?

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)

Not Specified

Health condition(s) or problem(s) studied

Injury, Occupational Diseases, Poisoning: Tendon lacerations

Interventions

Randomisation of adult patients with zone II flexor tendon lacerations to receive either the Teno Fix repair or standard suture repair. Assessment of outcomes by blinded, independent observer.

Added 29 July 2008: trial stopped in 2006 due to poor recruitment.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Tendon rupture rate and digital range of motion at 12 weeks post-repair.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/09/2003

Reason abandoned (if study stopped)

Poor recruitment

Eligibility

Key inclusion criteria

Adult patients with acute Zone II flexor tendon lacerations in the hand.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. Adults above 60 yrs of age
2. Flexor tendon lacerations outside Zone 2
3. Complex injuries, eg crush, mutilation, skin loss, amputations, revascularisation
4. The presence of established infection in injured hand
5. Associated digital fractures
6. Delayed surgery
7. Severe intercurrent medical illness
8. Drugs, eg immunosuppressives, steroids, which can affect healing
9. Previous injuries to affected hand
10. Pre-existing arthritis in affected hand
11. Allergy to metals in the stainless steel suture of Teno Fix (chromium, copper, cobalt, nickel, iron)

Date of first enrolment

01/03/2003

Date of final enrolment

01/09/2003

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Plastic Surgery

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK) Own account

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration