

A randomised comparison of three incisions for frontozygomatic (FZ) fracture fixation

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/08/2012	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
N0436118104

Study information

Scientific Title

Study objectives

To assess the three surgical approaches to the FZ region in terms of adequacy of surgical access, level of difficulty, duration of procedure and level of scarring. To determine which incision gives best cosmetic result for our patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Frontozygomatic (FZ) fracture fixation

Interventions

Randomised controlled trial. Random allocation to:

1. Incision 1
2. Incision 2
3. Incision 3

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

1. Ease of surgery
2. Duration of surgery
3. Improved access surgically
4. Cosmetic outcome of surgery

Key secondary outcome(s)

Not provided at time of registration

Completion date

28/02/2004

Eligibility**Key inclusion criteria**

Patients are self selected by their injury. Fractures requiring operation are included in the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

30/08/2002

Date of final enrolment

28/02/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Oral & Maxillofacial Surgery

Leeds

United Kingdom

LS2 9LU

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration