

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/08/2012	<b>Condition category</b> Surgery	<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**  
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

**Study design**

Randomised controlled parallel group trial

**Primary study design**

Interventional

**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