# Rapid IMF™: Does it improve cross infection precautions in maxillofacial trauma surgery?

Prospectively registered Submission date Recruitment status 30/09/2004 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 30/09/2004 Completed [X] Results Individual participant data **Last Edited** Condition category 14/07/2011 Surgery

### 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 N0226132769

### Study information

Scientific Title

### Study objectives

Study hypothesis amended as of 2nd January 2008:

Glove perforations and percutaneous injuries occur commonly during the treatment of facial fractures, especially during Inter-Maxillary Fixation (IMF) with wires. The Rapid IMFTM device does not use any wires and may provide better cross infection control than wiring methods.

Study hypothesis provided at time of registration:

An assessment of the glove perforation and percutaneous injury rate when rapid immobilisation mandibular fracture (IMF)/traditional wiring IMF techniques are used/will be carried out - to identify the safest technique.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Each of the participating Oral and Maxillofacial Units obtained approval from their Local Research Ethics Committees (LREC) as follows:

- 1. Oral and Maxillofacial Unit of Manchester Royal Infirmary (Central Manchester and Manchester Children's University Hospitals NHS Trust): Central Manchester LREC, approved on 9 September 2002 (ref: 02/CM/242)
- 2. Oral and Maxillofacial Unit of Wythenshawe Hospital (University Hospital of South Manchester NHS Trust): South Manchester LREC, approved on 10 October 2002 (ref: 02/SM/349)
- 3. Oral and Maxillofacial Unit of Leicester Royal Infirmary: Leicester LREC

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Oral and maxillofacial surgery

#### Interventions

20 patients in each of 3 Units (total 60) will be treated with Rapid IMF™. 20 controls in each Unit (total 60) will be treated with eyelet wires.

### Intervention Type

Procedure/Surgery

#### Phase

**Not Specified** 

#### Primary outcome(s)

The incidence of perforations/operation specific to the type of IMF

### Key secondary outcome(s))

Secondary outcome measures added as of 2nd January 2008:

- 1. Number and types of exposure sustained by the surgeon, the assistant and the scrub nurse and their cause
- 2. Incidence of unnoticed glove perforations
- 3. Time and degree of difficulty for IMF application
- 4. Numbers of surgical complications

### Completion date

01/11/2004

### **Eligibility**

### Key inclusion criteria

Inclusion criteria amended as of 2nd January 2008:

- 1. Age 18 and over
- 2. Provision of written informed consent
- 3. Dentate patients with fractures of the mandible which require ORIF, where post operative Inter-Maxillary Fixation is not considered necessary and temporary intraoperative Inter-Maxillary Fixation could be achieved with either Eyelet wiring or Rapid IMF™ (as judged by the investigator)

Inclusion criteria provided at time of registration:

- 1. Patients undergoing open reduction and internal fixation (ORIF) of mandibular fractures
- 2. Twenty patients in each unit (60) will be treated with Rapid IMF
- 3. Twenty controls in each unit (60) will be treated with Eyelet wires

### Participant type(s)

Patient

### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

### Lower age limit

18 years

#### Sex

**Not Specified** 

#### Key exclusion criteria

Exclusion criteria added as of 2nd January 2008:

- 1. Decreased level of consciousness
- 2. Learning difficulties and history of significant psychiatric or somatic disease, which may interfere with the detection of complications and assessment of functional result, as judged by the investigator

#### Date of first enrolment

## Date of final enrolment 01/11/2004

### Locations

**Countries of recruitment** United Kingdom

England

Study participating centre New Cross Hospital West Midlands United Kingdom WV10 0QP

### Sponsor information

### Organisation

Department of Health

### Funder(s)

### Funder type

Government

### **Funder Name**

South Manchester University Hospitals NHS Trust (UK)

### **Results and Publications**

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### **Study outputs**

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Abstract resultsabstract P58001/09/2004NoNo