

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/07/2011	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr N Pigadas

**Contact details**  
New Cross Hospital  
Wednesfield Road  
Wolverhampton  
West Midlands  
United Kingdom  
WV10 0QP  
+44 (0)1902 695408  
npigadas@doctors.org.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/11/2002

**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

**Age group**

Not Specified

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

120

**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**

01/11/2002

**Date of final enrolment**

01/11/2004

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

New Cross Hospital

West Midlands

United Kingdom

WV10 0QP

**Sponsor information****Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**

Government

**Funder Name**

South Manchester University Hospitals NHS Trust (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Abstract results</a>	abstract P580	01/09/2004		No	No