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

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

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
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United Kingdom
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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?
Abstract results	abstract P580	01/09/2004		No	No