Unilateral fracture of the mandible: a comparison of intermaxillary fixation with screws or arch bar

Published: 11-02-2010
Last updated: 06-05-2024

The aim of the present study is to demonstrate the effectiveness of screw IMF.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON36594

Source
ToetsingOnline

Brief title
Mandible fracture: screws or arch bar?

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
lower jaw fracture, mandible fracture

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: (IMF) screws, arch bars, mandible-fracture, traumatology

Outcome measures

Primary outcome

Postoperative pain will be monitored by using a Visual Analogue Scale and a

7-points scale.

Secondary outcome

Occlusion, quality of life, gingival status, parodontium status, maximal mouth

opening and fracture healing will be monitored.

Study description

Background summary

Intermaxillary fixation (IMF) is used in the treatment of mandibular fracture. Two techniques, using arch bars or screws, are currently used for IMF. Whereas arch bars are in general the primary choice, screws for intermaxillary fixation are used increasingly. These techniques have never been compared. There is lack of evidence concerning the treatment outcome and complications using screws as IMF. We hypothesize that screw IMF is equally effective compared to arch bar IMF but accompanies less complications.

Study objective

The aim of the present study is to demonstrate the effectiveness of screw IMF.

Study design

Prospective randomized clinical trial. Blinding of the patients, physicians and observers is not possible.

Intervention

One group will be treated with arch bar IMF. The other patient group will be treated with screw IMF. The IMF will remain in situ for 6 weeks. All fractures

will be fixated with mini-plates if needed.

Study burden and risks

The postoperative follow-up will be the same as the treatment protocol for mandibular fractures as used in our department, i.e. every week postoperatively during 6 weeks. The patients have to ffil in a questionnaire concerning the quality of life and pain 1 week, 3 weeks and 6 weeks postoperatively. During their visit the gingival and parodontium status will be measured. All complications will be registered, e.g. infection, fracture of the screw, gingivitis, periodontitis, bone loss, damage of the roots and loss of the screws.

Contacts

Public
Vrije Universiteit Medisch Centrum

Postbus 7057
1007MB Amsterdam
NL
Scientific
Vrije Universiteit Medisch Centrum

Postbus 7057
1007MB Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with mandibular fracture combined with or without collum fracture, patients with one collum fracture with dislocation, patients should be between 18-65 years old, patients should have given their written informed consent.

Exclusion criteria

not being able to give informed consent, known chronic pain syndrome, mental retardation, psychiatric abnormality, malignant disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-05-2010
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2010
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL28831.029.09