Open versus closed treatment of fractures of the mandibular condyle: A prospective, randomized, multicentre study

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To compare open and closed treatment of fractures of the manibular condyle. With special attention to the subjective experience of temporomandibular joint dysfunction in patients.

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

Summary

ID

NL-OMON47753

Source
ToetsingOnline

Brief title
Treatment of fractures of the mandibular condyle

Condition

- Bone and joint therapeutic procedures

Synonym
fracture mandibular condyle, lower jaw fracture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fracture, mandibular condyle, treatment

Outcome measures

Primary outcome

The difference between open and closed reduction calculated by the Mandibular Function Impairment Questionnaire (MFIQ) (Stegenga et al. (1993) en Kropmans et al. (1999)).

Secondary outcome

I. Questionnaires

a. General health questionnaire

b. Research Diagnostic Criteria for Temporomandibular Disorders: RDC/TMD

c. Oral Health Impact Profile: OHIP-14

d. Symptom Checklist: SCL-90 (somatisation, sleep, depression, anxiety)

II. Anatomical reduction of the mandibular condyle (radiographic assessment)

III. Function temporomandibular joint (functional assessment)

IV. Neurological functions (neurological assessment)

V. Costs of both interventions and cost effectiveness

Study description

Background summary

Fractures of the mandibular condyle are common injuries that account for between 25% and 35% of all mandibular fractures. Treatment options for fractures of the mandibular condyle consist of either closed reduction or open reduction with internal fixation (ORIF).

Several studies have demonstrated advantageous clinical results with closed treatment of condylar fractures. Some studies however have shown complications of the closed reduction; including malocclusion, particularly open bites, reduced posterior facial height and facial asymmetry, chronic pain and reduced mobility.
Open reduction of the condylar fractures has been recommended in selected cases and different indications have been proposed. As well as the closed reduction, the open approach has not infrequently been associated with complications; a cutaneous scar and temporary paralysis of the facial nerve.
At present a consensus regarding the most appropriate method for the management of fractures of the mandibular condyle is missing. There is a lack of high quality evidence for the effectiveness of either approach. Most of the studies on this subject have been retrospective case series using a single approach rather than a comparison of the two techniques. Further research, comparing the two treatmen options is required to be able to make an informed choice between the open and closed reduction.

The aim of this prospective study was to compare open and closed treatment of fractures of the manibular condyle. With special attention to the subjective experience of temporomandibular joint dysfunction in patients.

Study objective

To compare open and closed treatment of fractures of the manibular condyle. With special attention to the subjective experience of temporomandibular joint dysfunction in patients.

Study design

Randomised clinical trial with follow up examinations at 2 weeks, 6 weeks, 6 months and 12 months.

Intervention

Open reduction

- Internal fixation (ORIF = titanium plates)
- Decisions about individual surgical procedures and surgical approaches are left to the surgeon

- No maxillomandibular fixation
- Physiotherapy is allowed

Closed reduction

- Maxillomandibular fixation (with steel wires or firm elastics for a maximum of 14 days)
- Physiotherapy is allowed

Postoperative instructions regarding mouth opening, no rinsing in the first 24 hours and a full liquid diet, are given to all patients.

Study burden and risks

Number of visits
- Follow up examinations at 2 weeks, 6 weeks, 6 months and 12 months.

Physical examination
a. Functional assessment: temporomandibular joint
b. Neurological assessment

Questionnaires
1. Mandibular Function Impairment Questionnaire (MFIQ)

2. Remaining:

a. General health questionnaire
b. Research Diagnostic Criteria for Temporomandibular Disorders: RDC/TMD
c. Oral Health Impact Profile: OHIP-14
d. Symptom Checklist: SCL-90 (somatisation, sleep, depression, anxiety)

Possible complications

Closed reduction:
Malocclusion, particularly open bites, reduced posterior facial height and facial asymmetry, chronic pain and reduced mobility.

Open reduction:
Bleeding, infection, cutaneous scar and temporary paralysis of the facial nerve.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age of patients older than 18 years
fracture of mandibular condyle (confirmed on X-ray)
presentation within one week of injury

Exclusion criteria

known anatomical abnormality with malocclusion and/or temporomandibular joint dysfunction
insufficient dentition
contraindications for general anaesthesia
mentaly disabled (unable to give informed consent)

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):	02-11-2015
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2019
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	NL38030.018.13