

Open and closed treatment of fractures of the mandibular condyle: A cross sectional study

Published: 24-08-2016

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To evaluate the treatment of fractures of the mandibular condyle. With special attention to the subjective experience of temporomandibular joint dysfunction in patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42969

Source

ToetsingOnline

Brief title

Cross sectional study concerning fractures of the mandibular condyle

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym

mandibular fracture

Health condition

Gewricht/bot traumatologie

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Geen

Intervention

Keyword: condyle, cross sectional, Fracture, treatment

Outcome measures

Primary outcome

Present function by the Mandibular Function Impairment Questionnaire (MFIQ) (Stegenga et al. (1993) en Kropmans et al. (1999)).

Secondary outcome

I. Questionnaires

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

III. Function temporomandibular joint (functional assessment)

IV. Neurological functions (neurological assessment)

V. Chewing test

Study description

Background summary

Background of the study

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.

Study objective

To evaluate the treatment of fractures of the mandibular condyle. With special attention to the subjective experience of temporomandibular joint dysfunction in patients.

Study design

Cross sectional, with a patients recall.

Study burden and risks

None

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients that presented between 2008 and 2015 with an mandibular condyle fracture in the Academic Medical Center in Amsterdam

Exclusion criteria

Below the age of 18 years, not understanding Dutch

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-03-2017

Enrollment: 130

Type: Actual

Ethics review

Approved WMO	
Date:	24-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-02-2017
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	NL57252.018.16