

Unilateral condylar mandibular fracture: anatomical position, functionality and quality of life.

Is anatomical reduction of conservatively treated unilateral condylar mandibular fracture related to functional and to subjective outcome?

Published: 14-02-2018

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The aim of this study is to describe whether anatomical reduction in closed treated unilateral condylar mandibular fracture and objectively measured masticatory performance are related.

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

Summary

ID

NL-OMON47249

Source

ToetsingOnline

Brief title

CoCo-study

Condition

- Fractures

Synonym

condylar mandibular fracture, fractured condylar neck

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: condylar mandibular fractures, conservative treatment, functionality, quality of life

Outcome measures

Primary outcome

- Anatomic parameters:

1. Anatomic position of the fracture on radiologic imaging by means of comparison after mirroring of the contralateral side in millimetres (continuous) and degrees (continuous).
2. Occlusion disorder (yes/no).

- Masticatory performance tested with Mixing Ability Test: outcome in *pixels* (continuous)

Secondary outcome

- Functional parameters:

1. Pain registration with the VAS-score in millimetres (continuous)
2. Clinical examination of the mandible: laterotrusion, protrusion, maximal opening of the mouth measuring interincisal distance, deviation of the chin when opening) in millimetres (continuous), tenderness of the TMJ.

- Subjective parameters:

1. RAND36 questionnaire (continuous)
2. MFIQ questionnaire (continuous)

Study description

Background summary

The condyle is the most fractured site of all mandibular fractures with a percentage that varies between 16% and 43%.(Boffano et al. 2015) Management for condylar mandibular fractures was traditionally conservative or closed treatment with intermaxillary fixation (IMF). An open approach with internal fixation (ORIF) became more favourable since the introduction of internal rigid fixation devices because of better anatomical reduction of the fracture.(Al-Moraissi and Ellis lii 2015) In current management there is no consensus for reaching best treatment outcome. Treatment decision remains dependant of the surgeon*s experience.(Baker, McMahon, and Moos 1998)(Kommers, Boffano, and Forouzanfar 2015)

Insufficient anatomical reduction of the facture after closed treatment could render a clinical functional acceptable result for the patient, although long term follow-up studies are limited.(Rutges et al. 2007)(Forouzanfar et al. 2013) Functionality is often studied, while functionality does not necessarily correspond to subjective outcomes for the patient and their quality of life.(Kommers, van den Bergh, and Forouzanfar 2013) This was also concluded in other medical fields.(Breek et al. n.d.; Kelly et al. 2005) Additionally, there is insufficient insight in objectively and subjectively measured masticatory performance in these patients and which factors influence these outcomes.

This study aims to describe whether objective en subjective outcomes are related. This could potentially contribute in taking treatment decisions for condylar mandibular fractures. If conclusive, we will strive to implement national guidelines.

Study objective

The aim of this study is to describe whether anatomical reduction in closed treated unilateral condylar mandibular fracture and objectively measured masticatory performance are related.

Study design

observational cross-sectional study

Study burden and risks

It concerns a one time visit to the clinic of oral and maxillofacial surgery UMC Utrecht. The patient completes 2 medical questionnaires, gets a CBCT-scan of the mandible, the mixing ability test is performed, and in the end examination of the maxillary complex. This will take about 45minutes. The risk of participation is the risk of one low dose conebeam CT-scan (0.7mSv)

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

- Unilateral condylar mandibular fracture (neck and/ or base) between 1996 and 2013
- Closed treatment
- ≥ 18 year of age at time of trauma
- Dysocclusion at time of trauma
- Patients with sufficient Dutch writing and reading skills

Exclusion criteria

- No informed consent
- Legally incapable and/ or (treatment for) psychiatric disease
- Le Fort I, II en/ of III fractures, apart from unilateral fractures of the zygoma
- Pregnancy

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 24-09-2018

Enrollment: 60

Type: Actual

Ethics review

Approved WMO

Date: 14-02-2018

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 12-09-2018
Application type: Amendment
Review commission: METC NedMec

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	NL60070.041.17