VALIDATION OF CLINICAL DECISION AIDS FOR MIDFACIAL AND MANDIBULAR INJURY,
THE REDUCTION V TRIAL, A prospective multicentre cohort trial.

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The primary objective of this study is to validate the clinical decision aids developed in the REDUCTION I & II studies for patients with midfacial and/or mandibular injury in the emergency department.

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

Summary

ID

NL-OMON56277

Source
ToetsingOnline

Brief title
REDUCTION-V

Condition

- Other condition

Synonym
facial injury, Maxillofacial injury

Health condition

Maxillofaciale fracturen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Clinical decision aid, Mandibular injury, Maxillofacial injury, Midfacial injury

Outcome measures

Primary outcome

The primary outcomes are 1) the sensitivity, specificity and negative predictive value of the REDUCTION I decision aids for diagnosing and excluding the presence of a midfacial or mandibular fracture compared to the CT and CBCT and 2) the sensitivity, specificity and negative predictive value of the REDUCTION II decision aids for excluding the presence of a midfacial or mandibular fracture requiring active treatment compared to the standard care.

Secondary outcome

Rating the probability of having a maxillofacial fracture before and after the physical examination (ranging from 0 - 10), where 0 indicates a low probability of having a maxillofacial fracture and 10 indicates a high probability of having a maxillofacial fracture. As an additional option, 11 is added to indicate that the maxillofacial fracture is known to the attending physician prior to assessment.

Severity of maxillofacial injury based on the Facial Injury Severity Score (FISS). Each diagnosed maxillofacial fracture or laceration longer than 10 cm

is given a score from 1 to 6 on the FISS, and the sum of all scored fractures or lacerations gives an indication of the overall severity of the acquired maxillofacial injury.

The overall injury severity, based on the Abbreviated Injury Scale (AIS) and the Injury Severity Score (ISS). The AIS is a 6-point scale, where 1 represents the least severe injury and 6 the most severe, where the injury results in death. The AIS is used to calculate the ISS as a measure of overall injury severity.

Presence of dental injury

Presence of skull fractures

Study description

Background summary

Currently, computed tomography (CT) is considered the gold standard for the diagnosis of midfacial and mandibular fractures. The easy availability of the CT scan has led to an exponential increase in the number of CT examinations for patients with suspected midfacial and mandibular fractures. This in turn has led to an increase in the cost and radiation exposure within this population of patients. In both midfacial and mandibular fractures, specific clinical parameters have shown to be contributing but not decisive in ruling out fractures. Testing for a set of these specific clinical parameters, for example, in a decision aid, could be of aid in deciding to preform imaging and/or predict the required treatment. Thus, a decision aid for stratifying midfacial and mandibular injury could reduce the number unnecessary imaging in patients with midfacial and mandibular injuries and thereby reduce costs and radiation exposure. For this reason, the REDUCTION study group was established as a multidisciplinary collaboration between the emergency medicine, radiology,

trauma surgery and oral and maxillofacial surgery departments to reduce unnecessary imaging, and resulted in the REDUCTION I and II studies (Approval METc 2017/249), In these studies, four decision aids have been developed based on clinical parameters, in order to rule out: I) the presence of midfacial fractures, II) the presence of midfacial fractures that require active treatment, III) the presence of mandibular fractures, and IV) the presence of mandibular fractures that require active treatment. Initial analysis showed a proportional reduction of 5-15% in maxillofacial CT scans for maxillofacial injuries in the ED. However, the external validity of these clinical decision aids needs to be established before they can be incorporated into routine clinical practice.

Study objective

The primary objective of this study is to validate the clinical decision aids developed in the REDUCTION I & II studies for patients with midfacial and/or mandibular injury in the emergency department.

Study design

Prospective multicenter cohort study

Intervention

Each patient with a midfacial and/or mandibular injury will receive a standardised physical examination based on the REDUCTION I and II clinical decision aids. The midfacial and/or mandibular clinical decision aids are used to predict the presence of midfacial and/or mandibular fractures and the presence of midfacial and/or mandibular fractures requiring active treatment. After physical examination in the emergency department (ED), patients are scanned with either a maxillofacial CT or low-dose cone beam computed tomography (CBCT). Later, the choice of treatment for a maxillofacial fracture, active or conservative (standard of care), will be reviewed by chart review.

Study burden and risks

This study cohort will contain two subgroups.

The first subgroup will include patients who have a regular clinical indication for maxillofacial CT in the ED as part of standard care. Patients in this subgroup will not be exposed to additional radiation. These are patients with midfacial or mandibular injuries with a high clinical suspicion of a midfacial or mandibular fracture. For this subgroup, the entire study is standard of care. In the previous REDUCTION I study, maxillofacial CT was performed in 80% of patients with mandibular injury and 85% of patients with midfacial injury presenting to the ED.

The second subgroup will include patients who do not receive a maxillofacial CT scan in the ED as part of standard care because of a low clinical suspicion of fracture.

An estimate of the percentage of patients in this subgroup can be made based on the REDUCTION I study. In this study, maxillofacial CT was not performed in 20% of patients with mandibular injuries and 15% of patients with midfacial injuries because the suspicion of a maxillofacial fracture was low.

Given the endpoint of this study, i.e. absolute certainty of the presence or absence of a maxillofacial fracture, all patients with midfacial or mandibular injuries will need to undergo maxillofacial imaging. For validation, it would be best to screen all patients with the gold standard, a maxillofacial CT scan. However, taking into account the ALARA (as low as reasonably achievable) principle in imaging to minimise radiation dose to patients, CBCT is more appropriate.

The second subgroup of patients will be asked to visit the outpatient clinic of oral, maxillofacial and maxillofacial surgery within a week. During this visit, patients will undergo a physical examination of the midface and/or mandible by an oral surgeon, followed by CBCT scanning of the affected area. CBCT scans are considered to have a significantly lower radiation dose than CT scans. Nevertheless, they have been shown to be more than sufficient for diagnosing maxillofacial fractures, even at very low doses. The UMCG uses a value of 0.07 millisieverts for maxillofacial CBCT, compared with doses of 0.4 millisieverts for a CT. For the second subgroup, CBCT is not part of standard care and is therefore considered an additional burden. However, the advantage of the additional CBCT for this subgroup of patients is that it ensures that fractures of the midface and/or mandible are not missed .

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

Patients with midfacial and/or mandibular injury with a possibility of midface or mandible fracture are eligible for inclusion if the following conditions are met
-Visible injuries to the face or in the oral cavity.
-A trauma mechanism suspected of causing facial fractures, e.g., punch to the face, fall to the chin, traffic accident, etc.
-An anamnesis that clearly indicates a facial trauma.
-Patients aged >= 18 years

Exclusion criteria

Patients with non-energetic maxillofacial injury i.e. cutting wounds or spontaneous epistaxis
Patients who are not admitted for the first time with maxillofacial injury within the inclusion period.
Patients whose initial assessment is performed in another hospital.
Patients who have declined access to medical records and are registered in the objection register .
Patients who have had reconstructive surgery in the now affected maxillofacial region.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2024
Enrollment:	1300
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL84033.042.23
Other	Wordt geregistreerd na goedkeuring