The efficacy of Cone beam CT compared to panoramic radiography for removal of impacted mandibular third molars: a randomized controlled trial*

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To evaluate the efficacy and cost-effectiveness of CBCT imaging compared to panoramic radiography prior to removal of third molars in reducing patient*s morbidity.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON37789

Source
ToetsingOnline

Brief title
CBCT prior to third molar removal

Condition

- Head and neck therapeutic procedures

Synonym
Impaction of third molars. Retention of wisdom teeth

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cone Beam CT, Inferior alveolar nerve injury, Panoramic radiography, Third molars

Outcome measures

Primary outcome

Postoperative inferior alveolar nerve injury, after lower third molar removal.

Secondary outcome

Oral Health related Quality of Life measures and cost issues of treatment. Oral

health related quality of life includes postoperative complications (e.g

infection) and health related aspects (OHIP, days of work)

Study description

Background summary

The removal of third molars is one of the most common surgical procedures for oral and maxillofacial surgeons, often followed by an uneventful convalescence. As with any surgical procedure, also this procedure too is associated with certain complications. One of the most distressing worries following third molar removal is damage to the inferior alveolar nerve (IAN) with subsequent neurosensory impairments in the lower lip and chin. The overall risk of temporary IAN injury associated with third molar removal ranges from 0.4% to 6%. The reported rate of permanent IAN injury, in which the sensory impairment lasts longer than 6 months, is less than 1%

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The most evident risk factor for injury of the IAN is the proximity of the root of the third molar to the mandibular canal. When a close relationship between the third molar and the mandibular canal is observed radiographically, the risk of IAN injury increases. It is important to assess the position, and establish the relationship, of the third molar with the mandibular canal preoperatively to minimize the risk of nerve injury. The panoramic radiograph is the standard

diagnostic tool for this purpose, which provides 2D information. Clinicians use various radiographic markers to indicate a close relationship between the third molar and the mandibular canal.
In the recent years, cone Conebeam Beam CT (CBCT) has been introduced, which provides a 3D visualization of the hard tissue. The CBCT scans are gaining popularity and are more often used in the preoperative assessment of the third molars and their relationship with the mandibular canal.
Unfortunately, evidence regarding the diagnostic efficacy of CBCT for impacted teeth is limited.6 In a previous study, we found no significant difference between the panoramic radiograph and CBCT in predicting IAN exposure during surgery were found.
The decision to perform a preoperative radiograph should be based on the *as low as reasonably achievable (ALARA) principle, meaning that the radiographic technique with the lowest radiation dose should be used to obtain the information needed. A panoramic radiograph. PR produces an effective dose of approximately 0,024 mSv. A CBCT scan of the mandible only, produces an approximate dose between 0,047mSv and 0,14829 mSv, thereby increasing the effective dose by a factor of 2-6 compared to panoramic radiography. Therefore, it is important to weigh up the potential benefits of using CBCT images against the risk of extra exposure.

Study objective

To evaluate the efficacy and cost-effectiveness of CBCT imaging compared to panoramic radiography prior to removal of third molars in reducing patient*s morbidity.

Study design

A parallel-group designed randomized trial. Patients consulting the Departments of Oral maxillofacial surgery at UMC Radboud hospital for third molar removal, receive a digital panoramic radiograph at their first clinical visit on a standard basis. If a close relationship between the mandibular canal and third molar root is observed, patients will be informed about the study and will be asked to participate. Patients will be randomized and divided in two groups. For one group there will be no differences from the standard procedure, the other group will receive a CBCT prior to third molar removal. One week after surgery patients will be tested on IAN injury by a blinded researcher for both groups.

Study burden and risks

A different procedure in this study compared to the standard treatment, is that the half of patients with an increased risk of IAN injury, will be subjected to higher radiation exposures with a factor of 2-6 with a CBCT. Although the radiation exposures are significantly higher in producing a CBCT compared to a

panoramic radiograph (PR) the effective doses are only between 3,2% to 7,5% of the yearly background exposure in the Netherlands, which can be compared to the radiation exposure from an intercontinental flight. The number of clinical visits in the study group is not different compared to the standard treatment protocol. As the CBCT will be made prior to surgery, for the study subjects an additional visit to the hospital is saved.
This research has a low burden for the subjects, but is of utmost importance for the general and oral health care and the financial burden for the society. Removal of third molars is one of the most performed surgical procedures in many countries. Without evidence, the overall radiation exposures caused by health care may raise unnecessary. On the other hand, the new imaging modality might reduce the risk of postoperative complications.

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

Adults having a close relationship between the mandibular canal and one or both lower third molars, as diagnosed from digital panoramic radiographs.

Exclusion criteria

Pregnancy, radiological evidence of cyst and tumors, indication for removal under general anesthesia, preoperative neurosensory alterations and the existence of an external CBCT

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2013
Enrollment:	167
Type:	Actual

Ethics review

Approved WMO

Date:	09-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL40492.091.12