# Coronectomy of the lower wisdom tooth in older adults

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
12/06/2024		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/06/2024	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
22/07/2025	Oral Health			

### Plain English summary of protocol

Background and study aims

Coronectomy is an alternative to complete surgical removal of a mandibular third molar (wisdom tooth) that is near the inferior alveolar nerve. It involves removing the crown of the tooth while leaving the roots intact. This study investigates the effect of coronectomy on postoperative quality of life in older adults.

Who can participate?

Patients aged over 60 years who require coronectomy of a mandibular third molar

What does the study involve?

Patients undergo coronectomy on a mandibular third molar. During the first week after surgery, patients fill in a questionnaire and they are followed up at 1 week, 3 months, 6 months, and 1 year (patients are followed up annually up to 5 years later).

What are the possible benefits and risks of participating?

There are no risks of participating. The surgery has to be performed. The benefits are that we gain insight into the impact on the Oral Health-Related Quality of Life after a coronectomy of a mandibular third molar in the older patient population.

Where is the study run from? Amstelland Hospital (The Netherlands)

When is the study starting, and how long is it expected to run? July 2018 to December 2021

Who is funding the study?
Amstelland Hospital (The Netherlands)

Who is the main contact?

Dr J.A.H. Lindeboom, j.a.lindeboom@amsterdamumc.nl

# Contact information

### Type(s)

Public, Scientific, Principal Investigator

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# Additional identifiers

# EudraCT/CTIS number

Nil known

### **IRAS** number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

W19 015# 19.033

# Study information

#### Scientific Title

Mandibular third molar coronectomy in older adults and effects on oral health-related quality of life

### Study objectives

This study aimed to assess the effect of coronectomy on the postoperative quality of life during the first postoperative week in older adults using the Oral Heal Impact Profile-14 (OHIP-14) questionnaire. Factors potentially influencing the postoperative OHIP-14 score, such as smoking, impaction pattern of the mandibular third molar, inclination of the mandibular third molar, and state of eruption, were also evaluated. Patients were monitored up to a minimum of 1 year after the surgery.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 23/01/2019, Academic Medical Center Medical Ethical Committee (Meibergdreef 9, Amsterdam, 1105AZ, Netherlands; +31 (0)205667389; metc@amsterdamumc.nl), ref: W19\_015#19.033

### Study design

Observational cohort study

# Primary study design

Observational

# Secondary study design

Cohort study

### Study setting(s)

Hospital

# Study type(s)

Quality of life

# Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet: j.a.lindeboom@amsterdamumc.nl

# Health condition(s) or problem(s) studied

Impacted mandibular third molar

### **Interventions**

Patients undergo coronectomy on a mandibular third molar. During the first week after surgery, patients fill in an Oral Health Impact Profile-14 (OHIP-14) questionnaire. This study's follow-up was at 1 week, 3 months, 6 months, and 1 year (patients are followed up annually up to 5 years postoperative).

### Intervention Type

Procedure/Surgery

### Primary outcome measure

Oral health related quality of life measured with the OHIP-14 questionnaire each day of the first postoperative week

### Secondary outcome measures

- 1. Postoperative pain measured using the visual analog score (VAS) during the 1st postoperative week
- 2. Swelling (self-reported yes/no) during the 1st postoperative week
- 3. Trismus (self-reported yes/no) during the 1st postoperative week
- 4. Postoperative bleeding (self-reported yes/no), during the 1st postoperative week
- 5. Infection (yes or no infection) assessed by the clinician at 1 week
- 6. Potential neurosensory deficits assessed by the clinician using tactile, two-point discrimination, thermal change detection and heat pain thresholds at 1 week, 3 months, 6 months, and 1 year
- 7. Postoperative self-care behaviors: use of analgesics and cooling the cheek with ice on the first postoperative day

# Overall study start date

01/07/2018

### Completion date

31/12/2021

# **Eligibility**

### Key inclusion criteria

- 1. An indication for coronectomy on a mandibular third molar
- 2. A minimum age of 60 years at the time of the surgery
- 3. Fluency in Dutch to complete the Dutch version of the OHIP-14 questionnaire

### Participant type(s)

**Patient** 

### Age group

Adult

### Lower age limit

60 Years

### Upper age limit

100 Years

### Sex

Both

### Target number of participants

30

### Total final enrolment

30

### Key exclusion criteria

- 1. < 60 years old
- 2. Did not have an indication for coronectomy of a mandibular third molar

### Date of first enrolment

01/02/2019

### Date of final enrolment

31/12/2020

# Locations

### Countries of recruitment

Netherlands

# Study participating centre Ziekenhuis Amstelland

Laan van de Helende Meesters 8 Amstelveen Netherlands

1181AM

# Sponsor information

### Organisation

Ziekenhuis Amstelland

### Sponsor details

Department of Oral and Maxillofacial Surgery Laan van de Helende Meesters 8 Amstelveen Netherlands 1188 AM +31 (0)207557027 kaakpo@zha.nl

### Sponsor type

Hospital/treatment centre

#### Website

https://www.ziekenhuisamstelland.nl/nl/

### **ROR**

https://ror.org/05e73v668

# Funder(s)

### Funder type

Hospital/treatment centre

#### **Funder Name**

**Amstelland Hospital** 

# **Results and Publications**

# Publication and dissemination plan

Planned publication in a peer-reviewed journal

# Intention to publish date

01/09/2024

# Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

# IPD sharing plan summary

Published as a supplement to the results publication

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/10/2024	22/07/2025	Yes	No