

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Forced eruption for surgical removal of impacted third molars close to the mandibular canal with temporary anchorage device on the ramus as a pilot study

Protocol summary

Study aim

Effectiveness of orthodontic extrusion of mandibular third molars teeth with orthodontic coil spring

Design

Phase one semi-experimental clinical trial study consisted of a group of 6 patients with mandibular impacted wisdom teeth and their selection is based on the risk of nerve injury in radiography and the effectiveness of orthodontic extrusion will be evaluated.

Settings and conduct

This study will be performed in the Department of Oral and Maxillofacial Surgery, school of Dentistry, University of Tehran. Surgery will be performed among patients candidates for mandibular third molar surgery in 2022 in two phases of orthodontic extrusion and extraction.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with mandibular wisdom teeth close to the mandibular nerve canal
Exclusion criteria: The horizontally impacted third molars of the mandible
Patients over 30 or below 17 years of age
Existence of systemic diseases including hypertension and diabetes

Intervention groups

The study included a group of patients with mandibular impacted wisdom teeth that are in close to the inferior alveolar nerve that will extrude with orthodontic spring then will extract.

Main outcome variables

Effectiveness of orthodontic extrusion of mandibular wisdom teeth close to the nerve canal using orthodontic springs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220428054691N1**

Registration date: **2022-10-01, 1401/07/09**

Registration timing: **prospective**

Last update: **2022-10-01, 1401/07/09**

Update count: **0**

Registration date

2022-10-01, 1401/07/09

Registrant information

Name

Mohammad Nomani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8601 6797

Email address

nmohammad2009@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-24, 1401/08/02

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Forced eruption for surgical removal of impacted third molars close to the mandibular canal with temporary anchorage device on the ramus as a pilot study

Public title

Orthodontic extraction of lower wisdom teeth with risk of lower lip paresthesia in new method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All Patient with impacted third molars

Exclusion criteria:

The horizontally impacted third molars of the mandible
Patients over 30 or below 17 years old Existence of systemic diseases including hypertension and diabetes

Age

From **17 years** old to **30 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **6**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, School of Dentistry,
Tehran University of Medical Sciences

Street address

Department of Oral and Maxillofacial Surgery ,School
of Dentistry, Tehran University of Medical Sciences,
North Karegar St, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

14399-55991

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.009

Health conditions studied

1

Description of health condition studied

Mandibular impacted wisdom teeth have required
extraction surgery with possibility of inferior alveolar
nerve injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

distracting of the apex of the mandibular wisdom tooth
from the inferior alveolar canal following orthodontic
traction

Timepoint

One month after orthodontic extrution

Method of measurement

Cone beam computed tomography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Orthodontic traction on mandibular
impacted wisdom teeth to separate from the inferior
alveolar canal with orthodontic spring and wire nickel
titanium and steel wire with a thickness of 0.4 mm that
connects one end of the spring to the ramus of mandible
and the other end of the spring to the impacted tooth.
The duration of this force is one month.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Surgery ,School
of Dentistry, Tehran University of Medical Scie

Full name of responsible person

Mohammad Nomani

Street address

Department of Oral and Maxillofacial Surgery ,School
of Dentistry, Tehran University of Medical Sciences,
North Karegar St, Tehran, Iran.

City

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Province

Tehran

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14399-55991

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+98 21 8601 6797

Email

Nmohammad2009@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr, Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Qods St.,
Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 8899 2970

Fax

+98 21 8898 7382

Email

Afotouhi@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Nomani

Position

Oral and maxillofacial surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is shareable

When the data will become available and for how long

All data is potentially shareable after unidentified patients

To whom data/document is available

All of people

Under which criteria data/document could be used

for surgical use are allowed

From where data/document is obtainable

Mohammad nomani Phone number

What processes are involved for a request to access data/document

Immediately

Comments