

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Mental Nerve Neurectomy: A Comparison Of Titanium Screw Versus Gutta Percha Obturation of Mental Foramen

Protocol summary

Study aim

To compare efficacy of Titanium Screw and Gutta Percha Sticks for obturation of Mental Foramen after Mental Nerve Neurectomy

Design

Single Blinded Randomized Controlled Trial

Settings and conduct

Oral and Maxillofacial Surgery Department of AFID, Pakistan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Unilateral Pain with Typical Signs of Trigeminal Neuralgia Past Medical History of Carbamazepine intake No Odontogenic Cause of Pain No Organic Cause of Pain Exclusion criteria: Atypical Facial Pain/Pain of Unknown Cause Bilateral Pain/Uncommon Distribution Longer than Normal Neuralgic Pain Pain of Odontogenic Origin Pain having Organic Cause

Intervention groups

One Group Had Titanium Screws for obturation of Mental Foramen in 2nd Group Gutta Percha Sticks were used for Obturation of Mental Foramen

Main outcome variables

Operators Ease Remission Of Pain Displacement of Obtating Material

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230926059527N1**
Registration date: **2023-09-28, 1402/07/06**
Registration timing: **prospective**

Last update: **2023-09-28, 1402/07/06**

Update count: **0**

Registration date

2023-09-28, 1402/07/06

Registrant information

Name

AMMAR Yasir

Name of organization / entity

Armed Forces Institute of Dentistry

Country

Pakistan

Phone

+92 346 7330822

Email address

seirraalphayankee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-01-07, 1402/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Mental Nerve Neurectomy: A Comparison Of Titanium Screw Versus Gutta Percha Obturation of Mental Foramen

Public title

Mental Nerve Neurectomy: A Comparison Of Titanium Screw VS Gutta Percha Obturation of Mental Foramen

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral Pain with Typical Signs of Trigeminal Neuralgia Past Medical History of Carbamazepine intake No Odontogenic Cause of Pain No Organic Cause of Pain

Exclusion criteria:
Atypical Facial Pain/Pain of Unknown Cause Bilateral Pain/ Uncommon Distribution of Pain Longer than Normal Neuralgic Pain Pain of Odontogenic Cause Pain having Organic Origin

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients assigned serial numbers as they got treatment. Evens in Titanium Screen Group and Odds in Gutta Percha Stick Group

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients were blinded as they were not informed about the treatment modality used for management of their ailment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of AFID

Street address

AFID CMH Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

918/Trg Dated 2020

Health conditions studied

1

Description of health condition studied

Trigeminal Neuralgia

ICD-10 code

G50.0

ICD-10 code description

Trigeminal neuralgia

Primary outcomes

1

Description

More Operators Compliance, Decreased Post Neurectomy Pain and Decreased Incidence of Displacement of Obturation material will be observed in Titanium Screw Group

Timepoint

3 months after Intervention

Method of measurement

Operators ease will be measured using questionnaire. Displacement will be observed on Orthopantomogram and Remission of Pain will be assessed by using VAS.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Titanium Screw Group, After obtaining Informed Consent regarding the procedure and needs of it ,Peripheral neurectomy followed by Mental Foramen obturation using Titanium Screw will be performed. Operator's Compliance will be assessed immediately after the procedure. Post Op Displacement and remission of pain will be assessed after three months

Category

Treatment - Surgery

2

Description

Intervention group: Gutta Percha Group, After obtaining Informed Consent regarding the procedure and needs of it ,Peripheral neurectomy followed by Mental Foramen obturation using Gutta Percha Sticks will be performed. Operator's Compliance will be assessed immediately after the procedure. Post Op Displacement and Remission of pain will be assessed after three months

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

AFID

Full name of responsible person

Syed Ammar Yasir

Street address

AFID, CMH Rawalpindi

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Phone

+92 346 7330822

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seirraalphayankee@gmail.com

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

AFID

Full name of responsible person

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Street address

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+92 314 5254504

Email

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

AFID

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**

AFID

Full name of responsible person

Syed Ammar Yasir

Position

Resident In Oral and Maxillofacial Surgery

Latest degree

Medical doctor

Person responsible for scientific inquiries**Contact****Name of organization / entity**

AFID

Full name of responsible person

Syed Ammar Yasir

Position

Resident in Speciality

Latest degree

Medical doctor

Other areas of specialty/work

Oral and MAXILLOFACIAL surgery

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Person responsible for updating data**Contact****Name of organization / entity**

AFID

Full name of responsible person

Syed Ammar Yasir

Position

Resident in speciality

Latest degree

Medical doctor

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study Protocol, Statistical Analysis Plan, Informed Consent Clinical Study Reports will be shared

When the data will become available and for how long

After Publication Of Study

To whom data/document is available

Medical Related Individuals

Under which criteria data/document could be used

Data Can be Used by Medical related Personal for the patients with Trigeminal Neuralgia

From where data/document is obtainable

Phone Whatsapp

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

Data access can be asked for by telephone

Comments