

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

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**City**

Rawalpindi

**Postal code**

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**Phone**

+92 346 7330822

**Email**

seirraalphayankee@gmail.com

**Other areas of specialty/work**

Oral and Maxillofacial Surgery

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**Province**

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**Postal code**

46000

**Phone**

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**Email**

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

AFID

**Full name of responsible person**

Syed Ammar Yasir

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**Postal code**

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**Phone**

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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

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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**