Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Carbamezapine 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 Obutating 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
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Pakistan
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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 Carbamezapine 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 materail 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 Remession 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Full name of responsible person
Syed Ammar Yasir
Position
Resident In Oral and Maxillofacial Surgery
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Person responsible for updating data

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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