

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of inferior alveolar nerve block success rate in mandible in Halsted technique and "Water On Tray" technique in the patients referred to the dental clinic.

Protocol summary

Study aim

The aim of this study is investigating the efficiency of "Water on tray" (WOT) technique in comparison with Halsted technique

Design

The clinical trial has a control group, Single-blinded in two 45-member groups, Randomize through the coin tossing. (Lion will be Halsted and Line will be WOT)

Settings and conduct

The referred patients to Dental Clinic of IB-GUMS are categorized in one of the injection group blindly with their consent, while they have inclusions criteria. The methods which are compared in the study are Halsted and "Water On Tray"

Participants/Inclusion and exclusion criteria

The patients who need the dental treatment in the mandible which both categorized in ASA I and acute pain is not their chief complaint.

Intervention groups

In the interventional group, "Water On Tray" injection with a bent needle create an approximate perpendicular accessibility surface on the medial surface of the ramus. The tip of the needle remains in contact with the bone, during the injection. The needle's bevel prevents subperiosteal injection. In the control group, Halsted method conducts according to the Malamed SF. Handbook of local anesthesia. 6th ed-2013.

Main outcome variables

The rate of pain felt during the injection and the rate of numbness in WOT technique in compare with Halsted technique.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037960N1**

Registration date: **2018-04-22, 1397/02/02**

Registration timing: **retrospective**

Last update: **2018-04-22, 1397/02/02**

Update count: **0**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Seyed Hadi Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3348 6421

Email address

drhadihoseini@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2017-11-26, 1396/09/05

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

Comparison of inferior alveolar nerve block success rate in mandible in Halsted technique and "Water On Tray" technique in the patients referred to the dental clinic.

Public title

Evaluation of the "Water On Tray" anesthetic technique efficacy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients which need the dental treatment in mandible All of the subjects of this study are in ASA I classification. All of the subjects must have the vital first mandibular premolar in the side of injection, in order to conducted electric pulp test.

Exclusion criteria:

Certain noncardiovascular disease (e.g., thyroid dysfunction, diabetes, sulfite sensitivity). Consuming MAO inhibitors Consuming of Tricyclic Antidepressant Consuming of Phenothiazines The subjects who state the acute pain as the chief complaint throughout history

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Actual sample size reached: **85**

More than 1 sample in each individual

Actual sample size in each individual: **2**

The first inferior alveolar nerve block injection in a side of the subject.

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the subjects, if they have inclusion criteria, will enter in one the injection groups via the result of the coin toss(Lion will be Halsted and Line will be WOT)

Blinding (investigator's opinion)

Single blinded

Blinding description

After receiving consent, all surveyors are informed that they are likely categorized in the studied group randomly, with considering the fact that no excessive danger exists and only the injection method is different.

Placebo

Not used

Assignment

Parallel

Other design features

In Water On Tray technique, because of the bent needle to 90 degrees and the possibility of approximate perpendicular injection, while the bone contact remains, The Halsted problem solved.The main idea and the name of this technique are adapted from the liquids nature, spreading on a surface-once they pour; on the other words, the anesthetic solution spreads on the ramus surface after injection and deliver to the inferior alveolar nerve and the lingual nerve.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

across from the 17th Shahrivar Hospital-Shahid Siadati St-Namjou St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.GUMS.REC.1396.329

Health conditions studied

1

Description of health condition studied

The comparison of inferior alveolar nerve block success rate in mandible in Halsted technique and Water ON Tray technique

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The rate of the inferior alveolar nerve block in the first injection via Water On Tray technique.

Timepoint

The numbness evaluation conducts every 30 seconds after 2 minutes.

Method of measurement

We ask the subjects about the lack of feeling the stick test (Dental explorer for extraoral evaluation and the 25 gauge needle for intraoral), then the moment record as the numbness time in the minute unite.

Secondary outcomes

1

Description

The pain rate during the injection

Timepoint

After injection

Method of measurement

Asking the patient according to Numeric Scale Rate of pain

<http://www.gums.ac.ir/ib>

Intervention groups

1

Description

Intervention group: In this group, we conduct the inferior alveolar nerve block with the long needle (25mm, gauge 27) which bent by own cap (to achieve an approximate perpendicular surface on the medial surface of the ramus) Also, the tip of the needle remains the contact to the bone, during the injection. The main idea and the name of the technique are adapted from the liquids nature, which spread on a board as soon as the pour; In this technique, the anesthetic solution will spread on the ramus surface after injection and receive to the inferior alveolar nerve and the lingual nerve. The used cartridge contains 2% lidocaine with 1:80000 epinephrine.

Category

Treatment - Other

2

Description

Control group: The control group undergoes Halsted technique, according to the method which mentioned in Malamed SF. Handbook of local anesthesia. 6th ed-2013. In this method, the needle is straight and doesn't contact bone during injection. In this group, like the interventional group, we use the long needle (25mm, gauge 27) and the cartridge contains 2% lidocaine and 1:80000 epinephrine.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The Dental Clinic of International Branch of Guilan University of Medical Sciences

Full name of responsible person

Heidar Mahmoudi Chenari

Street address

30 Metery Blvd

City

Bandar`e Anzali

Province

Guilan

Postal code

43146-37758

Phone

+98 13 4455 3185

Fax

+98 13 4455 3184

Email

ib@gums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The dental clinic of the International Branch of Guilan University of Medical Sciences (IB-GUMS)

Full name of responsible person

Heidar Mahmoudi Chenari

Street address

30 Metery Blvd

City

Bandar`e Anzali

Province

Guilan

Postal code

43146-37758

Phone

+98 13 4455 3185

Fax

+98 13 4455 3184

Email

ib@gums.ac.ir

Web page address

<http://www.gums.ac.ir/ib>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The dental clinic of the International Branch of Guilan University of Medical Sciences (IB-GUMS)

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

Rasht University of Medical Sciences

Full name of responsible person

Seyed Hadi Hoseini

Position

Associate professor of Guilan University of Medical Sciences-Dentistry Faculty

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

Street address
Fouman - Saravan Rd
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
drhadihoseini@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Seyed Hadi Hoseini
Position
Associate professor of Guilan University of Medical Sciences-Dentistry Faculty
Latest degree
Specialist
Other areas of specialty/work
Oral and Maxillofacial Surgery
Street address
Fouman - Saravan Rd
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
drhadihoseini@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Seyed Hadi Hoseini
Position
Associate professor of Guilan University of Medical

Sciences-Dentistry Faculty
Latest degree
Specialist
Other areas of specialty/work
Oral and Maxillofacial Surgery
Street address
Fouman - Saravan Rd
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
drhadihoseini@gums.ac.ir

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

The subjects are coded and just the data will present to the investigators.

When the data will become available and for how long

6 month after publication

To whom data/document is available

The Universities of medical sciences and valid research organizations

Under which criteria data/document could be used

Repeat the research project in the other place or the other situation or complete the project.

From where data/document is obtainable

Via the chief investigator`s email

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

Via organizational email and present the documents based on investigation in official organization

Comments