Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of pain perception during anesthetic needle insertion in local infiltration in anterior maxilla with and without diode laser irradiation in adults: a randomized clinical trial

Protocol summary

Study aim
Comparison of pain perception during anesthetic needle insertion in local infiltration in anterior maxilla with and without diode laser irradiation in adults

Design
Study groups include patients who receive needle injection into the vestibule of the maxillary incisors with and without diode laser irradiation with one week washing out period. Pain perception is immediately evaluated by the patient after injection. The patients is trained to know how to mark the numerical pain intensity scale before starting the treatment session. Randomized three-way blinded clinical trial is performed on 32 patients by random allocation list. The sealed envelopes randomly allocated to group A and B are provided by the statistical consultant and then released to the project manager.

Settings and conduct
Split mouth randomized clinical trial-Tehran University of Medical Sciences , school dentistry

Participants/Inclusion and exclusion criteria
1.Adult Patients who are physiologically in healthy condition determined using a questionnaires filled by the student 2.Adult patients who need restoring two maxillary incisors in the opposite quadrants.

Intervention groups
Diode laser irradiation-Shame laser

Main outcome variables
Perception of intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210618051613N1**
Registration date: **2021-06-30, 1400/04/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-30, 1400/04/09**
Update count: **0**

Registration date
2021-06-30, 1400/04/09

Registrant information
Name
Fariba Motevasselian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8801 5088
Email address
f-motevasselian@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-30, 1400/04/09

Expected recruitment end date
2021-10-02, 1400/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of pain perception during anesthetic needle insertion in local infiltration in anterior maxilla with and without diode laser irradiation in adults: a randomized clinical trial

Public title

Comparison of pain perception during anesthetic needle insertion with and without diode laser irradiation in adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult Patients who are physiologically in healthy condition determined using a questionnaires filled by the student Adult patients who need restoring two maxillary incisors in the opposite quadrants.

Exclusion criteria:

1-Patients that local anesthesia application with epinephrine vasoconstrictor is contraindicated such as patient with high blood pressure.. Patients who have mental illness such a depression, anxiety or epilepsy3 Patients who take analgesics (pain killer) Patients who smoke tobacco Patients who have severely destroyed painful teeth, teeth required endodontic treatment Patients who have painful soft or hard tissue lesions Patienrs who wear removable dentures caused denture stomatitis Patients with orofacial pain

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **32**

More than 1 sample in each individual

Number of samples in each individual: **2**

Maxillary incisors in two opposite quadrants

Randomization (investigator's opinion)

Randomized

Randomization description

32 empty envelops are given to the statistician and he randomly allocates them to A and B groups based on diode laser irradiation or shame laser. These sealed envelopes are then released to the project manager. Thus, a random allocation list is prepared. Random block sequence is formed using a table of random numbers. A sealed envelope is randomly selected by the project manager and it is presented to the person who applies the laser irradiation. After laser treatment (shame laser or active irradiation), the injection is performed by the student, while the student and the patient are completely blind regarding type of laser treatment. Therefore, half of the patients receive shame laser before injection in the first week and receive active laser irradiation on the following week. The treatment sequence is reverse for the second group of the patients.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patients are blinded to type of intervention. The patient is completely informed about the research process and a consent form is achieved. However, the patient does not know that in which group he or she will be allocated. Portable dental diode laser device is available in the surgery. Diode laser is irradiated in the intervention group and it is turned off in the control group. The person who does the injection is blind as well. The patient evaluates the pain severity.

Placebo

Used

Assignment

Parallel

Other design features

Dent 88, Italy , 915nm wavelength, power of 1.5W and energy density of 238.8J/cm2 for 40 S of diode laser

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences, School of Dentistry

Street address

North Karegar street

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2021-04-04, 1400/01/15

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.003

Health conditions studied

1

Description of health condition studied

1- Pain perception during needle insertion of local anesthesia 2- The effect of laser irradiation on pain perception

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain perception by patient according to numerical pain intensity scale

Timepoint

Immediately after local infiltration

Method of measurement
numerical pain intensity scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group consisted of patients aged 20 to 50 year-old who referred to the restorative dentistry department of Tehran University of Medical Sciences for restoration of maxillary anterior teeth in two opposite quadrants. The teeth with carious lesion not extended to inner third of dentin were selected. It was determined by radiographic examination. Patients who meet the inclusion criteria are explained about the treatment procedures and written consent form is received from the volunteers who participated in this research program. Lidocaine (concentration of 1.80,000 epinephrine) (Darupakhsh Co.) is the anesthetics agent that is used in this study. One third of carpule (1.8mL) in injected for anesthesia. Diode laser characteristics were determined after conducting a pilot study on 6 volunteers. does not cause soft or hard tissue damage or pulpal tissue irritation after 40 seconds of radiation. Diode aser device is calibrated before treatment procedure. The minimum and maximum time interval between the laser irradiation and the injection is between 2 to 5 minutes. The mucobuccal fold is first dried with a cotton roll and the upper lip is retracted with the fingers and the laser tip is touched with mucusa at the injection area without pressure for 40S. Local infiltration is performed by the second operator afterwards using 27-gauge short needle. In this study, supraperiosteal injection method (local infiltration injection) is used for dental anesthesia of maxillary anterior teeth. The second appointment for restorative treatment is scheduled one week later for washing out period. The pain perception is marked in the numerical pain intensity scale by the patient immediately after injection. All the patients are trained how to mark the numerical pain intensity scale before treatment session.

Category
Treatment - Devices

2

Description
Control group: Shame laser

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran University of Medical Sciences, School of Dentistry

Full name of responsible person
Fariba Motevasselian

Street address
Forth floor, School of dentistry of Tehran Univetsity of Medical Sciences, North Karegar Street

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8801 5088

Fax
+98 21 8801 5800

Email
f-motevasselian@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Marzieh Alikhasi

Street address
North Karegar Street

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8801 5088

Fax

Email
dent-research@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Education, School of Dentistry, University of Tehran

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
Fariba Motevasselian

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Restorative dentistry

Street address
خیابان کارگرشمالی

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8801 5088

Email
f-motevasselian@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fariba Motevasselian

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
North Karegar Street

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8801 5088

Fax
+98 21 8801 5800

Email
f-motevasselian@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fariba Motevasselian

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
North Kareger Street

City
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Province
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Postal code
1439955991

Phone
+98 21 8801 5088

Email
f-motevasselian@sina.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
One of the reasons of contribution of participants in the research project and getting consent form is, hiding the personal information

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All the items agreed to be shared will be announced through proposal and the probable published paper.

When the data will become available and for how long
6 months

To whom data/document is available
Subjects involved in the research project and the researchers

Under which criteria data/document could be used
In order to increase the awareness of researchers about the effect of diode laser irradiation on pain perception during needle insertion of anesthetic agent

From where data/document is obtainable
The executor of the project

What processes are involved for a request to access data/document
Sending email to the executor of the project asking for the data required

Comments