

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Preparation and comparison of buccal patches containing lidocaine and dexmedetomidine with articaine and dexmedetomidine in reduction of injection pain and increment of patients compliance in dental procedures

Protocol summary

Study aim

Reducing injection pain and increasing patient cooperation in dental practices.

Design

A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 180 patients. Random number table is used for randomization.

Settings and conduct

This clinical study is randomized and double-blinded in Al-Zahra Hospital, Isfahan. 180 adult patients with an age range of 20-35 years are selected. People are randomly selected and receive 1x1 cm patches containing the drug, and after 10 minutes, a supra periosteal lidocaine injection is performed by a dentist in the patient's mouth. Two control groups receive the drug-free patch and injectable lidocaine.

Participants/Inclusion and exclusion criteria

Participants have participation for the study and have referred to receive dental services that require local anesthesia. Patients must be free of any systemic disease (cardiovascular disease, diabetes, etc.), physical and mental disease, allergy to lidocaine and articaine, dental phobia, inflammation, abscess, and history of surgery at the injection site. Also, they do not have a history of taking any painkillers and corticosteroids in the last week. Patients who have a special emergency during the injection process and can not complete the case are excluded from the study. Also, patients who have pain during visit are not included in the study.

Intervention groups

Qualified people are divided into 6 groups: 1) Patche containing 350 mg of lidocaine, 2) Patche containing 350 mg of articaine, 3) Patche containing 350 mg of lidocaine + 1 microgram per kilogram of dexmedetomidine 4) Patche containing 350 mg 1 gram of articaine + 1 microgram per kilogram of dexmedetomidine , 5) Control is divided into two subgroups, one group of people will

receive drug-free patch and the other group will only receive injectable lidocaine.

Main outcome variables

The patient's pain level (VAS Score criterion).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210118050067N2**

Registration date: **2022-08-19, 1401/05/28**

Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**

Update count: **0**

Registration date

2022-08-19, 1401/05/28

Registrant information

Name

Erfaneh Ghassami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7118

Email address

e.ghassami@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preparation and comparison of buccal patches containing lidocaine and dexmedetomidine with articaine and dexmedetomidine in reduction of injection pain and increment of patients compliance in dental procedures

Public title
Comparison of buccal patches containing lidocaine and dexmedetomidine with articaine and dexmedetomidine in dental procedures

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients should cooperate for the study. Visiting for dental services that require local anesthesia.
Exclusion criteria:
 Those with any systemic disease (cardiovascular disease, diabetes, etc.), physical and mental illness. Patients who have a history of taking any painkillers and corticosteroids in the last week. Patients who have allergy to lidocaine and articaine. Patients who have dental phobia. Patients who have inflammation, abscess, and history of surgery at the injection site.

Age
From **20 years** old to **35 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
We use the random number table method. Each patient is assigned a number, and based on the random number table, an envelope is considered for each patient. On the envelope, the name, surname, number associated with that patient and the patch are placed inside. This envelope is opened by the project manager (neither the patient nor the dentist can see the contents of the envelope). Then the dentist apply the patch to the patient and after its effect, dentist perform the injection.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the randomization description section, we explained about the envelope related to the patient and its contents. This envelope is opened by the project manager (neither the patient nor the dentist can see the contents of the envelope).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Faculty of pharmacy , Isfahan university of medical sciences, Hezarjarib St , Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-06-22, 1401/04/01

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.130

Health conditions studied

1

Description of health condition studied

Pain caused by local anesthetic injection.

ICD-10 code

Z98818

ICD-10 code description

Other dental procedure status

Primary outcomes

1

Description

Pain caused by injection.

Timepoint

20 minutes after lidocaine injection.

Method of measurement

After finishing the procedure, we ask the patients to mark the pain they experienced on the Visual Analogue Scale from 0 to 10.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group receive a patch containing 350 mg of lidocaine.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in this group receive a patch containing 350 mg of articaine.

Category

Treatment - Drugs

3

Description

Intervention group: Patients in this group receive a patch containing 350 mg of lidocaine + 1 microgram of dexmedetomidine per kilogram.

Category

Treatment - Drugs

4

Description

Intervention group: Patients in this group receive a patch containing 350 mg articaine + 1 microgram per kilogram of dexmedetomidine.

Category

Treatment - Drugs

5

Description

Control group: Patients in this group receive a drug-free patch.

Category

Treatment - Drugs

6

Description

Control group: Patients in this group receive only injectable lidocaine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Milad Etemadi

Street address

Al-Zahra hospital, Soffe Blvd, Keshvari Expy, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5581

Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Hazarjarib St, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

isrc@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Milad Etemadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Al-Zahra hospital, Soffe Blvd, Keshvari Expy, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3792 5581

Email

etemadi@dnt.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Milad Etemadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Al-Zahra hospital, Soffe Blvd, Keshvari Expy, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3792 5581

Email

etemadi@dnt.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Elham Panahandeh

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Ferdous St.2, E Allameh Amini St, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8158799678

Phone

+98 31 3261 4402

Email

elham_p98@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available