Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The Effect of local dexamethasone injection after immediate implant placement

Protocol summary

Study aim
Determining the effect of local dexamethasone injection after implant placement surgery (Immediate implant)

Design
A clinical trial with a control group, with parallel groups, double-blinded, phase 3 on 60 patients, randomized by block randomization method

Settings and conduct
All patients(both groups) receive the same surgery and drug except dexamethasone. An experienced surgeon with the same technique in the special clinic of the Sari Dental Faculty performs all surgeries. The person who follows the patients and records their pain and swelling levels will not be aware of the patient's group, and only the surgeon will be aware of the patient's groups.Also, none of the patient and control groups know whether the local injection was done. Patients' pain will be evaluated by VAS (Visual Analogue Scale), criteria and accompanying clinical conditions will be described for the patient, and according to the classification made by Pasqualini, patients will rate their pain and swelling from 0 to 5.These tests will be done within 48 hours,4 days later and then 7 days after the surgery through a phone call.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individulas aged 18 to 60 years who have no threatening systemic disease or allergy to dexamethasone. Exclusion criteria include pregnant people, threatening systemic disease, weak immune system, AIDS, sensitivity to the drugs used in the study, and recent use of antibiotics and anti-inflammatory drugs.

Intervention groups
In the control group, subjects will not receive any corticosteroids. In the intervention group, immediately after suturing, dexamethasone will be injected with the help of an insulin syringe in the depth of the vestibule adjacent to the implanted tooth, and 1/3 vials of topical dexamethasone (8 mg from Alborz Darou Pharmaceutical Co.) will be used.

Main outcome variables
Pain; Swelling; Satisfaction with surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221228056958N1**
Registration date: **2023-02-18, 1401/11/29**
Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**
Update count: **0**

Registration date
2023-02-18, 1401/11/29

Registrant information

Name
Najmeh Sadat Valed Saravi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3331 4614

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n.valed@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of local dexamethasone injection after immediate implant placement

Public title

The Effect of local dexamethasone injection after immediate implant placement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People from 18 to 60 years old

Exclusion criteria:

Pregnant people, , ,, sensitivity to the drugs used in the study, and . Threatening systemic disease AIDS Weak immune system Recent use of antibiotics and anti-inflammatory drugs Cushing's syndrome Cataracte Psychosis Acute or chronic infection Tuberculosis (active and treated) Oral herpes simplex

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Block randomization (blocks of 4); Individual Randomization tool: The software of random allocation 2 Procedure of making a random sequence and hiding it: Using the software, codes A and B will be generated, where code A means the application of the dexamethasone group and code B means the application of the control group for each individual. Finally, the codes will be placed in the sealed envelope and the number of each patient will be written on the envelope. As each patient enters, the doctor will open the envelope and apply the desired treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who follows the patients and records their pain and swelling levels will not be aware of the patient's group, and only the surgeon will be aware of the patient's groups. Also, none of the patient and control groups know whether the local injection was done(There is a placebo).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Jouybar Intersection, Imam Sqr.

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2022-12-10, 1401/09/19

Ethics committee reference number

IR.MAZUMS.REC.1401.398

Health conditions studied

1

Description of health condition studied

Pain and swelling after immediate implant placement surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score

Timepoint

2 , 4 and 7 days after surgery

Method of measurement

Visual Analogue Scale

2

Description

Swelling score

Timepoint

2 , 4 and 7 days after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For local anesthesia, lidocaine 2% with epinephrine 1:100,000 is used. All patients (both groups) receive the same surgery and drug except dexamethasone. The implant used in the Bone level study will be with SLA level, two-stage surgery (screw closure), and cover the implant with gum. The minimum amount of initial stability for implants was considered to be 15 newtons. If the distance between the implant and the extracted tooth cavity is more than 2 mm, it is filled with xenograft grafting material. After completing the surgery and washing the area with normal saline, the incision site is sutured with 0-5 nylon thread and immediately injecting a dose of dexamethasone (1/3 vial of dexamethasone 8 mg Alborz Daro Pharmaceuticals) with an insulin syringe in the depth of the vestibule near the implanted tooth is done. Prescription medicine is amoxicillin 500 every 8 hours for 1 week and 0.2% chlorhexidine mouthwash (twice a day).

Category

Treatment - Drugs

2

Description

Control group: Anesthesia and surgery procedures and prescribed drugs are similar to the intervention group, but dexamethasone is not injected and instead, 1/3 vial of 2% lidocaine with epinephrine 1:100,000 is injected with an insulin syringe in the depth of the vestibule adjacent to the implanted tooth.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sari Dental Clinic
Full name of responsible person
Najmeh Sadat Valed Saravi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Najmeh Sadat Valed Saravi
Position
Assistant Professor
Latest degree
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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

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

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

Data Dictionary

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