Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of vitamin C on the repair of extracted tooth socket

Protocol summary

Study aim
Determining the effect of vitamin C on the repair of an extracted tooth socket

Design
A controlled, double-blind, randomized, phase 2 clinical trial on 54 patients. For randomization, random allocation version 1 software was used and for blinding, a placebo similar to vitamin C tablets in similar glass containers was used, where each batch is coded and only the researcher is aware of this coding process

Settings and conduct
This research is single-blind randomized clinical trial study. After examining the patients referred to Periodontology Department of Yazd School of Dentistry according to the entry and exit criteria and obtaining informed consent

Participants/Inclusion and exclusion criteria
Inclusion criteria: healthy patients aged 14 to 40 without medical conditions with noninfected bilateral symmetric premolars who require tooth extraction for orthodontic treatment, have no history of smoking or alcohol consumption, women are not pregnant or breastfeeding, patients have no psychiatric disease, and do not use corticosteroids or contraceptives containing estrogen. Exclusion criteria: patients who missed more than 1 dose of vitamin C

Intervention groups
Tooth extraction will be done using a standard technique and under local anesthesia، each extracted wound site is measured 3 times, immediately after extraction, on day 7 and day 21 after extraction In the control group, gel foam impregnated with normal saline and placebo is used, in the systemic drug group, gel foam impregnated with normal saline and 750 mg vitamin C tablets are used, in the topical drug group, gel foam impregnated with 1% vitamin C solution and placebo is used In all 3 groups, the foam gel is inserted into the socket with a 4 zero vicryl suture in a figure eight shape to tighten the gel foam in the area

Main outcome variables
Socket depth; Mesiodistal dimension; Buccolingual dimension; Pharmaceutical group; Age; Sex

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221212056786N1**
Registration date: **2023-07-29, 1402/05/07**
Registration timing: **prospective**

Last update: **2023-07-29, 1402/05/07**
Update count: **0**
Registration date
2023-07-29, 1402/05/07

Registrant information
Name
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-11, 1402/05/20
Expected recruitment end date
2024-02-09, 1402/11/20
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin C on the repair of extracted tooth socket

Public title

The effect of vitamin C on the repair of extracted tooth socket

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy patients aged 14-40 without medical conditions (including the absence of gastrointestinal diseases such as peptic ulcer, etc.) with bilateral symmetrical non-infectious premolars who need tooth extraction for orthodontic treatment. Also have no history of smoking or alcohol consumption Women are not pregnant or breastfeeding Patients do not have psychiatric disorders Patients do not use corticosteroids, anticonvulsant drugs such as phenytoin, contraceptive drugs containing estrogen and other antioxidant supplements in the period close to the study Patients do not have history of allergy to toluidine blue The selected teeth do not have bone loss or defects

Exclusion criteria:

Patients who will miss more than 1 dose of vitamin C

Age

From **14 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using the random allocation version 1 software under Windows, we generate a random sequence using a simple random allocation method. The result of the software is in the form of a software that specifies the numbers 1 to 54 along with the letters A, B and C, and the first qualified person will be assigned number 1, and the next people will get numbers 2 to 54. And the researcher places each qualified person in the specified group based on the random allocation table. In order to blind the random allocation, we ask the help of a third person who does not know about the interventions and the table is provided to him. When the eligible person comes, the intervention group that is with A, B and C groups will be asked by phone or SMS, and the person will be placed in the desired group.

Blinding (investigator's opinion)

Single blinded

Blinding description

For the purpose of blinding, the placebo is made in the form of round tablets with a yellow coating similar to vitamin C tablets of Amin Pharmaceutical Company and poured into similar glass containers, and each batch is coded. They don't know about received and done coding.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Dentistry-Shahid Sadoughi University of Medical Sciences

Street address

Faculty of Dentistry, Imam Reza Blvd., Kharat Blvd., Daheh Fajr Blvd., Yazd

City

yazd

Province

Yazd

Postal code

8914881167

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1401.056

Health conditions studied

1

Description of health condition studied

The repair of extracted tooth socket

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Socket depth

Timepoint

Immediately after extraction, 7 days and 21 days after tooth extraction

Method of measurement

From the marginal gingiva to the point where the probe enters the socket in mm

2

Description

Mesiodistal dimension

Timepoint

Immediately after extraction, 7 days and 21 days after tooth extraction

Method of measurement

Measurement of the mesiodistal dimension of the silent tooth at the CEJ level of the adjacent teeth in millimeters

3

Description

Buccolingual dimension

Timepoint

Immediately after extraction, 7 days and 21 days after tooth extraction

Method of measurement

Measurement of the buccolingual dimension of the silent tooth at the CEJ level of the adjacent teeth in millimeters

4

Description

Pharmaceutical group

Timepoint

At the beginning of the study

Method of measurement

local/systemic

5

Description

Age

Timepoint

At the beginning of the study

Method of measurement

The number of years in a person's life

6

Description

Sex

Timepoint

At the beginning of the study

Method of measurement

A person's physical phenotype

Secondary outcomes

empty

Intervention groups

1

Description

Control group: placebo receiver

Category

Placebo

2

Description

First intervention group: Topical vitamin C receiver

Category

Treatment - Drugs

3

Description

Second intervention group: Systemic vitamin C recipient

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Faculty of Dentistry

Full name of responsible person

seyed mohammad arab farashahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

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

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
seyed mohammad arab farashahi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
All data can be shared
When the data will become available and for how long
From September 2021 to 1 year after the publication of the article
To whom data/document is available
For all people, including those working in academic and scientific institutions and industry

Under which criteria data/document could be used

Email and call

From where data/document is obtainable

mohammad arab farashahi, 09133735190, sma.farashahi_69@yahoo.com

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

After sending the email, the data is transferred

Comments