Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Preparation and in-vitro and in-vivo evaluation of a lipid-liquid crystal gel dressing containing eugenol and iodoform aim to treatment of alveolar osteitis

Protocol summary

Study aim

Our goal is to prepare and evaluate a lipid liquid crystal base dressing gel that contains eugenol as an analgesic and iodoform as an antiseptic, with wound healing capacity. The formulation can satisfactorily be used as a substitute for Alvogyl paste (which is not available in the Iranian market) which creates artificial blood clot to prevent re-bleeding.

Design

A parallel, triple-blind, randomized, controlled, phase 3 clinical trial on 60 patients. Balloting was used for randomization.

Settings and conduct

Recording the patient's information upon entering the Mashhad Dentistry School; Applying the medicine in the dental socket based on the experiment or control group; Recording the pain level according to VAS in specific time intervals and repeating if necessary. Triple-blind study Test or control dressing is placed in the patient's socket according to the randomization. Test and control dressing are delivered to the clinical caregiver in similar containers. The data analyzer receives patient information based on the code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age between 18 to 60 years old. 2. Patients suffering from dry socket who refer to Mashhad dentistry school. 3. Signing the informed consent. exclusion criteria: 1. Smoking 2. Pregnancy and breastfeeding 3. History of allergy to foods and drugs 4. Suffering from systemic diseases 5. Any active infective disease 6. Taking medications that interact with the healing process

Intervention groups

1. Control group: applying a sufficient amount of alveogel in the tooth socket. 2. Intervention group: applying a sufficient amount of liquid crystal gel dressing in the tooth socket.

Main outcome variables

1. Measuring patients' pain upon admission (according to VAS) and examining the intensity of pain after applying each type of dressing 2. Checking the number of times the dressing is used

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221027056320N1**
Registration date: **2022-12-02, 1401/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-02, 1401/09/11**
Update count: **0**

Registration date

2022-12-02, 1401/09/11

Registrant information

Name

Amirhossein Chavoshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3890 9880

Email address

chavoshia961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-19, 1401/08/28

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Preparation and in-vitro and in-vivo evaluation of a lipid-liquid crystal gel dressing containing eugenol and iodoform aim to treatment of alveolar osteitis

Public title
Preparation and evaluation of a new dressing aim to treat dry socket
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants' age should be between 18 to 60 years old. Patients suffering from dry socket following a tooth extraction who refer to Mashhad dentistry school. Participants should sign the informed consent.
Exclusion criteria:
Smoking or addiction Pregnancy and breastfeeding History of allergy to foods and drugs Suffering from systemic diseases Active infective disease (such as hepatitis , AIDS ,TB) Taking medications which interact with healing process (such as corticosteroids , immunosuppressors , anticancer drugs , anticoagulants) Age under 18 or above 60 years old History of radiotherapy of head and neck region.
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
For the required number of samples, identical envelopes are prepared, half of them are marked as group one and the other half as group two, the envelopes are sealed, patients are randomly assigned to one of the two groups by choosing an envelope.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The participant randomly chooses one of the envelopes and based on the selected code, one of the drugs (test and control) is placed in the patient's socket. Since the patient does not know which drug is the test and which is the control, and it is not posible to see the drug inside the socket, the study is blind for the participant. The clinical caregiver is selected among the nurses. The test and control drugs are delivered to them in similar containers, and they will not know which drug is the control or the test. The outcome evaluator and data analyzer receive patient information based on the code and will not know which code is related to the control drug or the test drug.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committee of Mashhad university of medical sciences
Street address
Research and technology vice-chancellor, Qoreishi building, next to Hoveizeh cinema, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2022-04-30, 1401/02/10
Ethics committee reference number
IR.MUMS.REC.1401.097

Health conditions studied

1

Description of health condition studied
alveolar osteitis (dry socket)
ICD-10 code
K10.3
ICD-10 code description
Alveolar osteitis , Dry socket

Primary outcomes

1

Description
Measuring patients' pain upon admission (according to VAS) and examining the intensity of pain after applying each type of dressing
Timepoint
At 30, 60 minutes and 6, 12, 24, 48, 72 hours and 7 days

after application and it continues on a daily basis, until the patient has pain.

Method of measurement

Questionnaire designed based on Visual Analog Scale (VAS)

2

Description

Checking the number of times the dressing is used

Timepoint

After the complete relief of pain and at the end of the follow-up

Method of measurement

Recording the frequency of dressing use in Excel by the researcher

Secondary outcomes

1

Description

Checking the number of Analgesic used for each patient

Timepoint

After the complete relief of pain and at the end of the follow-up

Method of measurement

Asking the patient and recording in Excel by the researcher

Intervention groups

1

Description

Control group: applying sufficient amount of alveogel manufactured by the Turkish company "Kalsin" in the tooth socket so that it fills the socket and repeating it every 24 hours in case of pain and upon the request of the patient until the complete pain relief.

Category

Treatment - Drugs

2

Description

Intervention group: applying sufficient amount of liquid crystal gel dressing, prepared in Mashhad Faculty of Pharmacy, in the tooth socket so that it fills the socket and repeating it every 24 hours in case of pain and upon the patient's request until the complete pain relief.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Surgery, Mashhad Faculty of Dentistry

Full name of responsible person

Mahdi Gholami

Street address

Faculty of dentistry, in front of Mellat park, at the beginning of Vakil Abad blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Fax

+98 51 3882 9500

Email

ShirzadeA@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Research and technology vice chancellor, Qoreishi building, next to Hoveizeh cinema, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

GhayourM@mums.ac.ir

Web page address

https://v-research.mums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Amirhossein Chavoshi

Position
Intern

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

Street address
Unit 4, No. 5, at the Hekmat sq. corner, Piroozi Blvd, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9178843100

Phone
+98 51 3890 9880

Fax

Email
chavoshia961@mums.ac.ir

Person responsible for scientific inquiries

Contact

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chavoshia961@mums.ac.ir

Person responsible for updating data

Contact

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Fax

Email
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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
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

Title and more details about the data/document
All personal data of study participants can be shared after anonymization.

When the data will become available and for how long
Beginning of the access period, 6 months after the publication of the results.

To whom data/document is available
All applicants in academic and non-academic sectors can apply to receive data after authentication..

Under which criteria data/document could be used
For use in the academic sector, the source of the data must be mentioned and the copyright must be respected. If it is used in the industrial sector leading to product production, the royalties of the researchers involved in the study should be included.

From where data/document is obtainable

To receive data, send an email containing your introduction and the reason for needing data to the following address: Amirhossein Chavoshi The first researcher of the study ahch1378@gmail.com

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

1. Sending an email containing specifications and reasons for the need for data 2. Completing the sent questionnaire form 3. Authentication and consent of all researchers to release data 4. Sending data to the applicant

Comments