Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the Effectiveness of local aftingel ointment and First generation oral cephalosporins in Improving lip mucosal traumatic ulcers(laceration) in patients older than 17 years old

Protocol summary

Study aim
Assessment the effects of Aftingel on healing patients with traumatic wounds of the lip mucosa

Design
A clinical trial with control and intervention groups and with parallel groups, double-blind, simple randomization, phase 2 on 100 patients.

Settings and conduct
The effect of Aftingel on the healing of oral mucosal ulcers in patients who are visited in the emergency room of Alzahra and Kashani centers of Isfahan University of Medical Sciences. The study is double-blind and includes the patients, registerer of results (a constant questioner who is a person other than the researcher).

Participants/Inclusion and exclusion criteria
Inclusion criteria: patient consent to participate in the study, without underlying diseases, not taking any antibiotics, wounds that do not require debridement and size of them less than 5 cm, no malnutrition, simple wounds without any fractures and nerve damage, not using medication that interfere with wound healing.
Exclusion criteria: Incomplete information about the type of wound, patient's disinclination to participate in the plan at any time during the study, Wounds that have been created for more than 12 hours.

Intervention groups
Both control and intervention groups receive routine wound treatment, Except that the control group takes antibiotics but intervention group takes Aftingel instead of antibiotics.

Main outcome variables
Appearance, size and duration of complete wound healing, patient's satisfaction and his pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221004056086N1**
Registration date: **2022-10-19, 1401/07/27**
Registration timing: **prospective**

Last update: **2022-10-19, 1401/07/27**
Update count: **0**

Registration date
2022-10-19, 1401/07/27

Registrant information

Name
Parisa Nasr Isfahani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of local aftingel

ointment and First generation oral cephalosporins in Improving lip mucosal traumatic ulcers(laceration) in patients older than 17 years old

Public title
Effect of aftingel ointment in healing of mouth ulcers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient satisfaction to participate in the study Age older than 17 years Absence of underlying disease such as liver and kidney disease, Diabetes Mellitus, progressive neurologic disorders, GI disorders and coagulopathy and Wound healing disorders Not taking any antibiotics for any reason less than 24 hours from the onset of the ulcer Wounds without requirement to debridement and smaller than 5 cm without malnutrition Simple wound without nerve damage and fracture Not taking medicine with known interference in wound healing
Exclusion criteria:
Incomplete information about type of wound Patients who don't want to participate in this study at any time during the study Taking any antibiotics for any reason less than 24 hours from the onset of the ulcer Wounds that have been created for more than 12 hours Wounds larger than 5 cm
Age
From **17 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients with ulcers in the mouth area are collected and then randomly assigned to control and intervention groups, and during the sample selection, the patients in each group are matched in terms of sex, cause of ulcer, severity of infection, Age, physical condition and type of nutrition.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, 100 patients with ulcers in the mouth area are collected and then randomly assigned to control and intervention groups (50 people in each group) and a satisfaction form was prepared for each of the experimental units, and complete explanations about how to conduct the study and its interventions are presented to the patients so that the ethical context of the project is respected. Both groups were asked about wound changes (appearance, size and duration of complete healing of wound), pain (based on VAS) and patient's satisfaction (based on Likert scale) and records in the forms prepared for this purpose by a constant questioner, who is not a researcher, and unaware of group's type.
Placebo
Not 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
No.4, Isfahan university of medical science, Hezar jerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-10-11, 1401/07/19
Ethics committee reference number
IR.MUI.MED.REC.1401.259

Health conditions studied

1

Description of health condition studied
Traumatic wounds of the oral mucosa (laceration)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Wound length
Timepoint
On 0, 3 and 7th days of treatment
Method of measurement
graded ruler in centimeters

2

Description
Wound healing time
Timepoint

On 0, 3 and 7th days of treatment

Method of measurement

Based on the length of wound in centimeters until complete wound healing

3

Description

Patient satisfaction

Timepoint

On 0, 3 and 7th days of treatment

Method of measurement

Likert scale

4

Description

pain

Timepoint

On 0, 3 and 7th days of treatment

Method of measurement

Visual analouge scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: preparation of the patient and the doctor, local anesthesia and preferably nerve block of the involved area, cleansing by washing with normal saline and wound repair with the simple suture (if needed) with absorbable thread, mainly vicryl 0-4 or 0-5 with 4 knots at least (depending on wound depth, number of suture layers varies from one to three), rewash with normal saline serum, common oral antibiotic treatment (first generation cephalosporins) for 3 to 7 days Tetanus immunoprophylaxis (according to the standard protocol) is performed routinely in the emergency room and gargling warm salt water solution three times a day at home.

Category

Treatment - Drugs

2

Description

Intervention group: All procedures are similar to the control group, but instead of systemic antibiotic treatment, the patient is treated locally with Aftingel. Open the nozzle and slowly put a drop of Aftin gel on an Qtip and then press it gently for 20 seconds exactly on the wound area and repeat these steps 5 times a day. This is repeated and continued for two weeks, and other wound care items are similar to control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mehradad Nourozi

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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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
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
Reza Azizkhani

Position
professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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
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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

It will be available for researchers working in academic and scientific institutions and those working in industry.

Under which criteria data/document could be used

Data analysis is allowed for use in other scientific studies. The submitted request will be reviewed by principal and scientific officer of this project, and if both agree, the results will be provided to the applicant.

From where data/document is obtainable

pnasr0895@gmail.com(Parisa Nasr Isfahani)
azizkhani1980@gmail.com(Reza Azizkhani)

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

After demanders send request's e-mail and explain complete informations about type of required informations and reasons of request and how to use them, will be reviewed their request within a maximum of 3 working days, the documents will be provided to them through the possible channels.

Comments