

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Formulation and clinical evaluation of mucoadhesive gel containing licorice based nanoniosomes for treatment of oral ulcers

Protocol summary

Study aim

The aim of the present study is to formulate adhesive mucosal gel containing licorice nanoniosomes and its clinical evaluation in the treatment of oral ulcers.

Design

A randomized controlled clinical trial with a parallel group

Settings and conduct

The present study is a two-group clinical trial that will be performed on 40 patients with oral ulcers in Hamedan in 2020. Intervention Procedure will receive the gel mouthwash of Niosomal licorice extract Three times a day, half an hour before meals for a week. Control group: Initial oral care, as well as three times a day, half an hour before meals for one week, will receive the licorice extract mouthwash gel.

Participants/Inclusion and exclusion criteria

Age group between 18 and 65 years
Definite diagnosis of mild to moderate pest or mucositis by a dental specialist
Absence of other skin diseases such as psoriasis
No infection in the affected area

Intervention groups

Intervention Procedure will receive the gel mouthwash of Niosomal licorice extract Three times a day, half an hour before meals for a week, . Control group: Initial oral care, as well as three times a day, half an hour before meals for one week, will receive the licorice extract mouthwash gel.

Main outcome variables

Incidence and severity of oral ulcers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046143N1**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **prospective**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

Registration date

2020-01-26, 1398/11/06

Registrant information

Name

Seyed Yaser Vafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3426 6353

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and clinical evaluation of mucoadhesive gel containing licorice based nanoniosomes for treatment of oral ulcers

Public title

Formulation and clinical evaluation of mucoadhesive gel containing licorice based nanoniosomes for treatment of oral ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of mild to moderate aphthous or mucositis by a dental specialist
Absence of other skin diseases such as psoriasis
No infection in the affected area

Exclusion criteria:

Diabetic patients with heart failure
Pregnancy during the study
Side effects that are not tolerated by the patient
Immune deficiency
Malignant diseases

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications will be perfectly the same in the two groups. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan, Shahid Fahmideh Ave., Hamadan
University of Medical Sciences

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Province

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Postal code

38698-65178

Approval date

2020-01-11, 1398/10/21

Ethics committee reference number

IR.UMSHA.REC.1398.861

Health conditions studied

1

Description of health condition studied

oral ulcers

ICD-10 code

K12

ICD-10 code description

Stomatitis and related lesions

Primary outcomes

1

Description

Incidence and severity of oral ulcers

Timepoint

Before and up to a week after the intervention

Method of measurement

World Health Organization Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive niosomal mouthwash
Licorice extract three times each half hour before meals
for one week.

Category

N/A

2

Description

Control group: Primary oral care, as well as three times a day, half an hour before meals for a week, will receive a Licorice extract mouthwash gel.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital

Full name of responsible person

Seyed Yaser Vafaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Yaser Vafaei

Position

Assistant Prohessor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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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