Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparision of the efficacy of two treatment methods including baicalin mucoadhesive paste with betamethasone mouthwash and betamethasone mouthwash alone in patients with oral lichen planus

Protocol summary

Study aim

Comparision of the efficacy of two treatment methods including baicalin mucoadhesive paste with betamethasone mouthwash and betamethasone mouthwash alone in patients with oral lichen planus

Design

Randomized clinical trial, control group, on 36 patient

Settings and conduct

A case-control randomized clinical trial study will be conducted on patients with oral lichen planus referred to the Faculty of Dentistry in Tabriz University of mediccal science. Patients will be randomized into two groups. The participants in the case group will receive mucoadhesive baicalin paste with betamethasone mouthwash, and the control group will receive betamethasone mouthwash alone.

Participants/Inclusion and exclusion criteria

Patients with definite diagnosis of oral lichen planus based on clinical and histopathological findings Patients with at least one visible and measurable ulcerative or atrophic or reticular lichen planus lesion. Adult patients (over 18 years old) Patients who have not received immunosuppressive drugs Patients without underlying disease Patients with complete records including clinical and demographic information Smoking, alcohol consumption, caffeine Immune system suppression Presence of other simultaneous skin or mucosal lesions Received treatment for oral lichen planus in the last 12 weeks Lesions showing any dysplastic changes. Unwillingness to participate in the study

Intervention groups

Eligible patients will be randomized into two groups. The participants in the case group will receive baicalin mucoadhesive paste with betamethasone mouthwash, and the participants in the control group will receive betamethasone mouthwash alone.

Main outcome variables

Clinical score based on Thongprasom scale Pain score using Visual Analogue Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241114063707N1**
Registration date: **2024-11-25, 1403/09/05**
Registration timing: **prospective**

Last update: **2024-11-25, 1403/09/05**
Update count: **0**

Registration date

2024-11-25, 1403/09/05

Registrant information

Name

Mohadese Eslamzade hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3477 3883

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-20, 1403/09/30

Expected recruitment end date

2025-05-20, 1404/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the efficacy of two treatment methods including baicalin mucoadhesive paste with betamethasone mouthwash and betamethasone mouthwash alone in patients with oral lichen planus

Public title

Comparision of the efficacy of two treatment methods including baicalin mucoadhesive paste with betamethasone mouthwash and betamethasone mouthwash alone in patients with oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with definite diagnosis of oral lichen planus based on clinical and histopathological findings Patients with at least one visible and measurable ulcerative or atrophic or reticular lichen planus lesion. Adult patients (over 18 years old) Patients who do not receive immunosuppressive drugs Patients without underlying disease Patients with complete records including clinical and demographic information

Exclusion criteria:

Smoking, alcohol consumption, caffeine The presence of uncontrolled diabetes, hypertension and other underlying diseases that hinder participation in the study Immune system suppression Presence of other simultaneous skin or mucosal lesions Received treatment for oral lichen planus in the last 12 weeks Patients with oral candidiasis Viral infections Lesions showing any dysplastic changes. Unwillingness to participate in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

18 intervention envelopes and 18 control envelopes, which are identical , will be randomly numbered from 1 to 36. The randomization process will be done manually. The envelopes will remain sealed until the treatment begins. The distribution of the envelopes will follow the order of the patients on the list. Patients will be matched based on age and gender, and one of the researchers, who is aware of the treatment administered to the patient, will answer any questions the patients may have.

Blinding (investigator's opinion)

Single blinded

Blinding description

Eligible patients will be randomized into two groups. In this study, blinding will be done in such a way that the third researcher will be unaware of the treatment used for the patient and will only perform measurements and determine the clinical score. The questions of the patients will be answered by one of the researchers who is in the course of the treatment done for the patient. The third researcher and statistical analyst will be unaware of the content of the prescribed drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar street, Golgasht, Azadi Blv.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2024-08-19, 1403/05/29

Ethics committee reference number

IR.TBZMED.REC.1403.417

Health conditions studied

1

Description of health condition studied

oral lichen planus

ICD-10 code

L43.8

ICD-10 code description

Other lichen planus

Primary outcomes

1

Description

Clinical score based on Thongprasom scale

Timepoint

At the beginning of the intervention, 2 weeks later, 4 weeks later

Method of measurement

The clinical score will be based on Thongprasom's scale : Grade 0 = no lesion / normal mucosaGrade 1 = white striae / no erythematous areaGrade 2 = white striae with an atrophic area equal to or less than 1 cm2Grade 3 = white striae with an atrophic area greater than 1 cm2Grade 4 = white striae with an erogenous area equal to or less than 1 cm2Grade 5 = white striae with an erogenous zone greater than 1 cm2

2

Description

pain based on Visual Analogue Scale(VAS)

Timepoint

At the beginning of the intervention, 2 weeks later, 4 weeks later

Method of measurement

Pain will be evaluated using the Visual Analogue Scale including a 10 cm horizontal line (0 = no pain, 10 = the most severe pain experienced).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mucoadhesive baicalin with betamethasone mouthwash in patients with oral lichen planus. First, the plastibase base is prepared. This base is made of polyethylene and liquid paraffin, with the explanation that polyethylene is added to liquid paraffin at a rate of 5% by weight and volume, and the paraffin is melted and dissolved by heating. Then, it is spread on cold metal plates as a thin layer. When the plastibase base cools, it is formed. Baicalin is mixed with small amounts of base in a mortar and pestle using the geometric addition method, i.e., small amounts are mixed with small amounts of base to larger amounts in a mortar. Large amounts are placed under a mechanical stirrer to ensure the uniformity of baicalin distribution in the base. In the next step, the components of the mucoadhesive, namely pectin, gelatin, and sodium carboxymethyl cellulose, are added to the base in a ratio of one-third each and their total ratio to the base in a ratio equal to the geometric addition method under a mechanical stirrer. Care must be taken not to introduce water into the formulation at all stages. That is, completely dry containers should be used. It is better to completely dehydrate these mucoadhesive materials, namely pectin, gelatin and sodium carboxymethyl cellulose, in a 60 degree oven for 1 day before adding to the formula. The prepared formulation is filled in tubes and their containers are closed and stored in a dry environment, preferably a desiccator, until the patient uses it. Patients will receive baicalin mucoadhesive after brushing their teeth and then using betamethasone mouthwash. The mouthwash and then the mucoadhesive will be used three times a day. Patients will be followed up 2 and 4 weeks later. The parameters evaluated will include clinical scores based on Thongprasom's scale and pain using VAS. Patients will be given instructions on how to use the medications.

Category

Treatment - Drugs

2

Description

Control group: Betamethasone mouthwash in patients with oral lichen planus: Standard routine treatment regimen will be used. Betamethasone mouthwash will be used three times a day. Patients will be followed up 2 and 4 weeks later. The parameters evaluated will include clinical score based on Thongprasom's scale and pain using VAS. Patients will be given instruction on how to use the medications.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Faculty of Dentistry

Full name of responsible person

Mohadese Eslamzade Hesari

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Attar street, Golgasht, Azadi Blv., Tabriz faculty of dentistry

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Maryam Kouhsoltani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mohadese Eslamzaede Hesari

Position

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Latest degree

A Level or less

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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

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

Participants data file

When the data will become available and for how long

18 months after the study

To whom data/document is available

Data is published

Under which criteria data/document could be used

In case of citation

From where data/document is obtainable

Mohadese Eslamzade Hesari

m.eslamzade.d.s@gmail.com

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

By communicating with the person in charge of the update

Comments