

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison the effect of Chlorhexidine gluconate 0.2% mouthwash with Henna mouthwash as adjuvant therapy on oral lichen planus

Protocol summary

Registration timing: **retrospective**

Study aim

Evaluation and comparison of efficacy of Henna Mouthwash and Chlorhexidine Mouthwash on signs and symptoms of Oral Lichen Planus Lesions treated with topical corticosteroid

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Design

Randomized, double blinded, clinical trial. randomization will be done by pharmacologist.

Registrant information

Name

nahid karbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3244 8668

Email address

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Settings and conduct

The patients who presented with chief complaint from burning sensation of oral mucosa to Kerman dentistry university since 1390. topical steroid is prescribed for all of them as the main treatment. Neither patient nor clinician doesn't know which mouthwashes (Chlorhexidine or Henna) they receive. Pharmacist keeps mouthwashes in the same bottles(250 cc) and marks with numbers(1-40).

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

patients who have OLP, referred to Kerman dental school since 1390 and did not have histology signs of dysplasia. they did not use drugs with lichenoid reactions.

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-03-02, 1398/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

All patients will receive Betamethasone lotion as a topical steroid(the standard treatment for oral lichen planus). The control group patients will receive Chlorhexidine mouthwash and the intervention group,will receive Henna mouthwash as adjuvant therapy and according to this, the antimicrobial effect of these two mouthwashes is compared.

Scientific title

Comparison the effect of Chlorhexidine gluconate 0.2% mouthwash with Henna mouthwash as adjuvant therapy on oral lichen planus

Main outcome variables

Signs and symptoms of patients

Public title

evaluation the effect of henna mouthwash on oral lichen planus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181204041844N1**

Registration date: **2020-06-02, 1399/03/13**

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of atrophic and/or erosive lesions of the oral mucosa Painful lesions Histological confirmation of the diagnosis of oral lichen

Exclusion criteria:

presence of dysplasia in the histopathological study of OLP patients on long-term corticosteroid therapy the use of drugs capable of inducing lichenoid reactions

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed by the Randlist software and each patient will be entered in the treatment or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researcher and participants until the final analyses are completed. The researcher at the Kerman dental school, who is not aware of random sequences, will deliver the participants to 250cc opaque glass containers that have a similar appearance and contain a mouthwash. The taste and smell of henna and chlorhexidine mouthwashes are similar due to its 2% ethanol content.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman, the center of seven Alavi Gardens, Campus of Kerman University of Medical Sciences

City

kerman

Province

Kerman

Postal code

1355576169

Approval date

2639-09-19, 2018/06/28

Ethics committee reference number

1396.2417

Health conditions studied

1

Description of health condition studied

"oral lichen planus"

ICD-10 code

L43

ICD-10 code description

Lichen planus

Primary outcomes

1

Description

pain intensity

Timepoint

before intervention and 7,14 days after intervention

Method of measurement

Visual Analogue Scale

2

Description

clinical presentation or inflammation

Timepoint

before intervention and 7,14 days after intervention

Method of measurement

Thongprasom sign Scoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mouthwash 2% of the aqueous extract of Henna plant in the presence of other mouthwash compounds containing 0.1% w / w of methyl parahydroxybenzoate, 2% ethanol, 10% glycerol, distilled water twice a day (morning and evening) and each time 5 ml of the mouthwash for 30 seconds should be used. Gargle with betamethasone lotion four times a day (after meals and at bedtime) for one minute.

Category

Treatment - Drugs

2

Description

Control group: 0.2% chlorhexidine gluconate mouthwash and Iranian betamethasone lotion available on the market twice a day (morning and evening) and each time 5 ml of the mouthwash for 30 seconds should be used. Gargle with betamethasone lotion four times a day (after meals and at bedtime) for one minute.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry School of Kerman University of Medical Science

Full name of responsible person

Nahid Karbasi

Street address

Kerman, Islamic Republic Boulevard, End of Shafa Street, Kerman Dental School

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7618759689

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

moluk torabi

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Nahid Karbasi

Position

assistant

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Nahid Karbasi

Position

assistant

Latest degree

Medical doctor

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

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 collected deidentified IPD. IPD collected for primary outcome measure only.

When the data will become available and for how long

6 months after publication

To whom data/document is available

it will be available for people working in academic institutions.

Under which criteria data/document could be used

people working in academic institutions

From where data/document is obtainable

sov.karbasi@gmail.com dr.nahid.karbasi

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

request containing how the data will be used must be applied via email. citation in future publication is mandatory. data will be sent within 3 months.

Comments