Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

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

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

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).

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.

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.

Main outcome variables
Signs and symptoms of patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181204041844N1**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **retrospective**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

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

Registrant information

Name
nahid karbasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3244 8668

Email address
n.karbasi@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

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

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

Public title
evaluation the effect of henna mouthwash on oral lichen planus

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

City
kerman

Province
Kerman

Postal code
7618759689

Phone
+98 34 3211 9021

Email
sov.karbasi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
moluk torabi

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

City
kerman

Province
Kerman

Postal code
7618759689

Phone
+98 34 3211 9021

Email
sov.karbasi@gmail.com

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

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

City
kerman

Province
Kerman

Postal code
7618759689

Phone
+98 34 3211 9021

Email
sov.karbasi@gmail.com

Person responsible for scientific 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

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

City
kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Email

sov.karbasi@gmail.com

Person responsible for updating data

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

Street address

Kerman, Islamic Republic Blvd., End of Shafa St., Kerman School of Dentistry

City

kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Fax

+98 34 3211 8073

Email

sov.karbasi@gmail.com

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