

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of therapeutic effect of nigella sativa and corticosteroid in orabase on oral erosive atrophic lichen planus: A randomized triple blind clinical trial

Protocol summary

Study aim

treatment effect of nigella sativa ora base on oral lichen planus

Design

sample size 20 patients in each group randomization :simple clinical trial:phase 2 or 1

Settings and conduct

Patients with oral lichen planus lesions and inclusion criteria will be divided into two groups randomly and evaluated weekly for one month . Two kind of orabase will be provided completely the same and outcome assessors, patients and data analyzers will be blind to groups of treatment

Participants/Inclusion and exclusion criteria

inclusion criteria; New case of oral lichen plans clinically and histopathologically confirmed; limited to two lesions; maximum 3 cm diameter; exclusion criteria: medically compromised patients; lichenoid reaction; pregnant or breast feeding patients; children under 8 years old; nigella sativa hypersensitivity; immunosuppressant and analgesic drugs; Moderate to severe dysplasia.

Intervention groups

Nigella sativa ora basae group corticosteroid orabase group

Main outcome variables

Thongprossam Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080907001222N2**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **prospective**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

2019-03-11, 1397/12/20

Registrant information

Name

ATESSA PAKFETRAT

Name of organization / entity

MASHHAD DENTAL SCHOOL

Country

Iran (Islamic Republic of)

Phone

+98 915 520 1889

Email address

pakfetrata@mums.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2640-06-22, 2019/04/01

Expected recruitment end date

2641-03-21, 2020/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of nigella sativa and corticosteroid in orabase on oral erosive atrophic lichen planus: A randomized triple blind clinical trial

Public title

Comparison of therapeutic effect of nigella sativa and corticosteroid in orabase on oral erosive atrophic lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient with oral lichen planus two oral lesions maximum 3 cm diameter

Exclusion criteria:

systemic compromised patients lesion of posterior palate and oral floor pregnant and breast feeding patients children under 8 years old patients using immunosuppressant drugs lichenoid reaction lesions nigella sativa hypersensitivity

Age

From 8 years old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly divided into two groups. Randomization is performed Based on the random numbers table obtained from www.randomizer.org. Even number will be allocated in intervention group and odd number in control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Two orabase will be made completely the same ,for taste and color similarity we will add sub therapeutic dose of nigella sativa and color to orabase in control group so patients,outcome assessor and data analyser will be blind to drug type.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Mashhad medical university

Street address

Mashhad University of Medical Sciences, Faculty of

Dentistry

City

Mashhad

Province

Razavi Khorasan

Postal code

911735984

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.093

Health conditions studied

1

Description of health condition studied

lichen planus

ICD-10 code

L43

ICD-10 code description

Lichen planus

Primary outcomes

1

Description

severity of oral lesion

Timepoint

weekly up to one month

Method of measurement

tongprasom scale

Secondary outcomes

1

Description

burning sensation

Timepoint

Pain and burning sensation will be measured before intervention and then weekly for one month.

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

In intervention group patients will use nigella sativa orabase (5%) 3 times a day for one month

Category

Treatment - Drugs

2

Description

Control group: In this group patients will receive routine treatment which is orabase containing corticosteroid

(Triamcinolone 0-1%) 3 time a day topically for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and maxillofacial Diseases Department of Mashhad Dental School

Full name of responsible person

Dr. Atessa Pakfetrat

Street address

Department of Oral Medicine, School of Dentistry, Mashhad University of Medical Sciences, Vakilabad Blv

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Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Email

pakfetrata@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Department of Oral Medicine, School of Dentistry, Mashhad University of Medical Sciences, Vakilabad Blv

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Atessa Pakfetrat

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

No- There is no plan to make this available at the present time

When the data will become available and for how long

starting 9 months after publication

To whom data/document is available

academic researchers

Under which criteria data/document could be used

It is permitted to use the data in other studies with reference.

From where data/document is obtainable

pakfetrata@mums.ac.ir

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

Sending email to authors. the authors will send data via email during 4 weeks.

Comments