Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Public title
Comparison of therapeutic effect of nigella sativa and corticosterioid 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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+98 51 3882 9501

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

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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

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

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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
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