Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of hydroalcoholic extract of Nasturtium officinale on oxidative stress and inflammatory markers in asthma patients

Protocol summary

Study aim
Determining the effect of hydroalcoholic extract of Nasturtium officinale on oxidative stress and inflammatory markers in asthma patients

Design
A randomized controlled clinical trail with parallel, double_blind, randomized, phase 2 group on 60 patients used the random allocation rule.

Settings and conduct
patients with asthma referred to Shahid Mofteh Hospital in Yasuj are are randomly divided into two groups by random allocation method. patients in the intervention group (30 patients) receive Nasturtium officinale extract capsules and in the control group (30 patients) receive placebo (flour capsules) in the same form and amount. The treatment protocol in both groups in 500 mg capsules twice a day. Follow-up of patients is done every week during treatment and 8 weeks after the end of treatment. It should be noted that the patient and the researcher will not know about the assignment of groups and it is a double-blind study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: adult male/female (age 18-65 years); asthma diagnosis based on the Global Initiative for Asthma (GINA); asthma symptoms not fully controlled based on ACT (Asthma Control Test) score from 5 to24; no severe asthma exacerbation in the last four weeks; Complete conscious satisfaction Exclusion criteria: smoking history; pregnant women; taking any preparation containing NOE

Intervention groups
Intervention group: Capsules containing hydroalcoholic extract of Nasturtium officinale. Control group: Capsules containing flour

Main outcome variables
reduced symptoms of asthma: wheezing, coughing, shortness of breath, chest tightness or pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201215049726N1**
Registration date: **2021-01-01, 1399/10/12**
Registration timing: **prospective**

Last update: **2021-01-01, 1399/10/12**
Update count: **0**

Registration date
2021-01-01, 1399/10/12

Registrant information
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-20, 1399/11/01
Expected recruitment end date
2021-02-16, 1399/11/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of hydroalcoholic extract of Nasturtium officinale on oxidative stress and inflammatory markers in asthma patients

Public title
The effect of Nasturtium officinale extract on biomarkers in asthma patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both sexes age 18-65 years asthma diagnosis based on the Global Initiative for Asthma (GINA) asthma symptoms not fully controlled based on ACT (Asthma Control Test) score from 5 to24 no severe asthma exacerbation in the last four weeks Complete conscious satisfaction
Exclusion criteria:
smoking history pregnant women taking any preparation containing NOE
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the Restricted randomization method of the randomization Random allocation rule method. For this purpose, first determine a total sample size, then randomly assign a set of them to the intervention group and the rest to the control group. 30 balls for the intervention group and 30 balls for the control group are placed in a lottery container and then the balls are randomly removed from the container without replacement and the created sequence is recorded.
Blinding (investigator's opinion)
Double blinded
Blinding description
Capsules are individually packed envelopes and have an identification number. Capsules and envelopes of Nasturtium officinale extract and placebo are offered in exactly the same appearance and packaging, which will blind the participants and the researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of the Yasuj University of Medical Sciences
Street address
No.55, Imamat 6, Revolution Boulevard
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
75918-38799
Approval date
2020-12-06, 1399/09/16
Ethics committee reference number
IR.YUMS.REC.1399.163

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
ACT score
Timepoint
0-28 days
Method of measurement
Asthma Control Test questionnaire

Secondary outcomes

1

Description
protein carbonyl
Timepoint
0-28
Method of measurement
Spectrophotometry

2

Description
Total thiol content
Timepoint
0-28 days
Method of measurement

Spectrophotometry

3

Description
protein sulfhydryl
Timepoint
0-28 days
Method of measurement
Spectrophotometry

4

Description
Malondialdehyde
Timepoint
0-28 days
Method of measurement
Spectrophotometry

5

Description
The ferric reducing antioxidant power
Timepoint
0-28 days
Method of measurement
Spectrophotometry

6

Description
Glutathione peroxidase enzyme
Timepoint
0-28 days
Method of measurement
Spectrophotometry

7

Description
Superoxide dismutase enzyme
Timepoint
0-28 days
Method of measurement
Spectrophotometry

8

Description
Catalase enzyme
Timepoint
0-28 days
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Nasturtium officinale extract (NOE) capsules 500 mg twice daily for 4 weeks used as a supplementary treatment.
Category
Treatment - Drugs

2

Description
Control group: capsule of 500 mg of flour are used twice a day for 4 weeks as a placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofattah Clinic, Yasuj
Full name of responsible person
Reza Abbasi
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Sponsors / Funding sources

1

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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
Yasouj 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
Yasouj University of Medical Sciences
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Associate professor
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
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