

# 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 trial 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 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 is 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 to 24; 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

##### Name

Nasrin Shakerinasab

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3333 2892

##### Email address

nasrinsh299@gmail.com

##### 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 to 24 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

Kohgiluyeh-va-Boyerahmad

##### 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

**Street address**

No.55, Imamat 6, Revolution Boulevard

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**Province**

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**Email**

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Amirhossein Doustimotlagh

**Street address**

No.55, Imamat 6, Revolution Boulevard

**City**

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**Province**

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**Email**

amirhosseindoustimotlagh@ gmail.com

**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

**Full name of responsible person**

Amirhossein Doustimotlagh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Latest degree**

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**Other areas of specialty/work**

Biochemistry

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**Person responsible for updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Nasrin Shakernasab

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

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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