

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of *Portulaca oleracea* seeds on indicators of inflammation, 8-isoprostane and lung function in women with asthma : a randomized controlled trial

#### Protocol summary

##### Summary

This study aimed to determine the effect of *Portulaca oleracea* seeds on indicators of inflammation, 8-Isoprostane and lung function in women with asthma. In this study, women with age 18 years who having moderate asthma for at least 1 year as diagnosed by a physician according the Gina guideline include and Poepple with lung disorders and respiratory tract infections, kidney, liver or cardiovascular diseases, any change in medication type and dosage, having a history of oxalate stones and having an exacerbation in last month that led to hospitalization will be exclude then 70 patients randomly divided into two groups. In the intervention group, patients have treatment protocol and daily take 10 g *Portulaca oleracea* seeds in two doses (5 gm) in morning (fasting) and before dinner with a glass of water. In control group, Patients have their treatment protocol and drink two glasses of water in a day for 8 weeks. 8-Isoprostane, inflammatory factors including IL-4, TNF $\alpha$  and nitric oxide metabolites (nitrite and nitrate) will be measure in sputum samples that collected at first and end of study. In order to determine the pulmonary function tests, FEV1 and PEF are measured by the spirometer.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201206094105N7**  
Registration date: **2012-07-05, 1391/04/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-07-05, 1391/04/15

#### Registrant information

##### Name

Beit Allah Alipour

##### Name of organization / entity

Health & Nutrition Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

alipourb@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

#### Expected recruitment start date

2012-06-25, 1391/04/05

#### Expected recruitment end date

2012-11-21, 1391/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of *Portulaca oleracea* seeds on indicators of inflammation, 8-isoprostane and lung function in women with asthma : a randomized controlled trial

#### Public title

Effect of *Portulaca oleracea* seeds on indicators of inflammation, 8-isoprostane and lung function in women with asthma

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: • female • Age 18 years and above  
•having Moderate asthma for at least 1 year as diagnosed by a physician according the Gina guideline  
Exclusion criteria: • Smoking • having other lung disorders and respiratory tract infections • Pregnant or lactating • kidney, liver or cardiovascular disease • taking any multivitamin and mineral and dietary supplements containing antioxidants and omega-3 in 2 months ago • Any change in drug type and dosage • having a history of oxalate stones • having a exacerbation in last month that led to hospitalization • follow a diet • taking contraceptive pills

## Age

From **18 years** old to **80 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Golbad Ave

##### City

Tabriz

##### Postal code

#### Approval date

2012-06-25, 1391/04/05

#### Ethics committee reference number

9145

## Health conditions studied

### 1

#### Description of health condition studied

Asthma

#### ICD-10 code

J45

#### ICD-10 code description

moderate asthms

## Primary outcomes

### 1

#### Description

IL-4, TNF\_α and nitric oxide metabolites (nitrite and nitrate)

#### Timepoint

before and after of intervention

#### Method of measurement

sputum sample

### 2

#### Description

8 - Isoprostane

#### Timepoint

before and after of intervention

#### Method of measurement

sputum sample

### 3

#### Description

PEF and FEV1

#### Timepoint

before and after of intervention

#### Method of measurement

spirometer

## Secondary outcomes

### 1

#### Description

Food intake

#### Timepoint

Before and after of intervention

#### Method of measurement

24-hour dietary recall

### 2

#### Description

BMI

#### Timepoint

Before and after of intervention

#### Method of measurement

Scales and meters

## Intervention groups

## 1

### Description

In the interventional group, patients have treatment protocol and daily take 10 g *Portulaca oleracea* seeds in two doses (5 gm) in morning (fasting) and before dinner with a glass of water .

### Category

Treatment - Drugs

## 2

### Description

In control group, Patients have their treatment protocol and drink two glasses of water in a day for 8 weeks.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic

##### Full name of responsible person

Dr, khalil ansarin

##### Street address

Corner of Ostadan alley, Golgasht street, Azadi street,

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for Research, Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammadreza Rashidi

##### Street address

Golbad Street

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Dr. Beit Allah Alipour

#### Position

Assistant Professor

#### Other areas of specialty/work

#### Street address

Attar Neyshabouri Street, Golgasht Street

#### City

Tabriz

#### Postal code

5166614711

#### Phone

+98 41 1335 7580

#### Fax

#### Email

balipoor@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Seyyedeh Zahra Hosseini

#### Position

MSc student in community nutrition

#### Other areas of specialty/work

#### Street address

Attar Neyshabouri Street, Golgasht

#### City

Tabriz

#### Postal code

5166614711

#### Phone

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#### Fax

#### Email

z\_hosseini64@yahoo.com

#### Web page address

## Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

*empty*

#### Study Protocol

*empty*

**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*