

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Ginger efficacy in patients uncontrolled on standard moderate asthma treatment: a randomized, double-blind, placebo-controlled, cross-over study

#### Protocol summary

##### Summary

Objective: To compare the effects of ginger powder capsule (Zintoma, Goldaru) and indistinguishable placebo as add-on therapy in patients uncontrolled on standard moderate asthma treatment. Methods: For inclusion criteria, 40 consenting non-smoking patients aged between 16 and 70 years with a documented positive bronchodilator reversibility test with  $\geq 15\%$  improvement in FEV1 from 15 to 30 minutes after inhalation of at least 200  $\mu\text{g}$  of salbutamol are enrolled in the 10-week, randomized controlled cross over study. Exclusion criteria for the study are: emergency treatment for an asthma exacerbation within one month, COPD, upper airway infections in the last three weeks, hospitalization for asthma in the three months previous to enrolment, treatment with antihistamines, anticholinergics, theophylline and chromones, oral corticosteroids and  $\beta 2$  agonists, presence of autoimmune, cardiac, hepatic or renal disorders, malabsorption, drug-addiction, pregnancy and lactation. The patients complete a 10 week trial consisting of a 1 week single blind run in period, during which placebo are added to usual inhaled treatment (beclomethasone dipropionate, 200  $\mu\text{g}$ /twice daily + salmeterol, 50  $\mu\text{g}$ /twice daily) a 4 week double blind active phase in which subjects receive Zintoma capsule or placebo, a single blind 1 week washout period receiving placebo and a final 4 week double blind cross-over active treatment phase. Daily diaries are kept of peak expiratory flow and symptoms, and spirometry, validated symptom and health status questionnaire scores (ACT=Asthma Control Test) and adverse events are monitored at study visits. Paired T tests are used to compare the effects of placebo and Zintoma capsule on outcomes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201010194970N1**  
Registration date: **2010-12-12, 1389/09/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-12-12, 1389/09/21

##### Registrant information

##### Name

Davood Farzin

##### Name of organization / entity

Department of Pharmacology, School of Medicine,  
Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3088

##### Email address

dfarzin@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences

##### Expected recruitment start date

2010-11-22, 1389/09/01

##### Expected recruitment end date

2011-04-19, 1390/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Ginger efficacy in patients uncontrolled on standard moderate asthma treatment: a randomized, double-blind, placebo-controlled, cross-over study

**Public title**

Ginger efficacy in patients uncontrolled on standard moderate asthma treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 40 consenting non-smoking patients aged between 16 and 70 years with a documented positive bronchodilator reversibility test with  $\geq 15\%$  improvement in FEV1 from 15 to 30 minutes after inhalation of at least 200  $\mu\text{g}$  of salbutamol are enrolled in the 10-week, randomized controlled cross over study. Exclusion criteria for the study are: emergency treatment for an asthma exacerbation within one month, COPD, upper airway infections in the last three weeks, hospitalization for asthma in the three months previous to enrolment, treatment with antihistamines, anticholinergics, theophylline and chromones, oral corticosteroids and  $\beta 2$  agonists, presence of autoimmune, cardiac, hepatic or renal disorders, malabsorption, drug-addiction, pregnancy and lactation.

**Age**

From **16 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mazandaran University of Medical Sciences

**Street address**

Moallem Street, Moallem Square

**City**

Sari

**Postal code**

4817844718

**Approval date**

2010-05-26, 1389/03/05

**Ethics committee reference number**

20-89

**Health conditions studied****1****Description of health condition studied**

Asthma

**ICD-10 code**

J45

**ICD-10 code description**

Moderate asthma

**Primary outcomes****1****Description**

Spirometric tests

**Timepoint**

Weeks 1, 3, 5, 6, 8, 10

**Method of measurement**

Spirometry apparatus

**2****Description**

Immunologic tests

**Timepoint**

Weeks 1, 3, 5, 6, 8, 10

**Method of measurement**

laboratorial evaluation of IgE and sputum eosinophil

**3****Description**

Condition of asthma control

**Timepoint**

Weeks 1, 3, 5, 6, 8, 10

**Method of measurement**

Clinical memoir, physical examination, completion of asthma control questionnaires

**Secondary outcomes****1****Description**

Side effect of drugs

**Timepoint**

weeks 1, 3, 5, 6, 8, 10

**Method of measurement**

Clinical memoir, Physical examination

## Intervention groups

### 1

#### Description

Type of intervention: Ginger powder, oral 250 mg capsule, three times daily for 10 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sari Emam Hospital

##### Full name of responsible person

Dr. Nazanin Mansouri

##### Street address

The Clinic of Lung, Emam Hospital

##### City

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Mohamad Bagher Montazeri

##### Street address

Mazandaran University of Medical Sciences Number 2 Building, Moallem Square

##### City

Sari

#### Grant name

پژوهشی

#### Grant code / Reference number

89-20

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

Yes

#### Title of funding source

Mazandaran 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

##### Name of organization / entity

School of Medicine, Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Nazanin Mansouri

##### Position

M.D., Internal Medicine Resident

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## Person responsible for scientific inquiries

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Ph. D.

##### Other areas of specialty/work

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## Person responsible for updating data

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**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*