Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ≥ 15% improvement in FEV1 from 15 to 30 minutes after inhalation of at least 200 µg 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, theophyline and chromones, oral corticosteroids and β2 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 µg/twice daily + salmeterol, 50 µg/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

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Name of organization / entity

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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 ≥ 15% improvement in FEV1 from 15 to 30 minutes after inhalation of at least 200 µg 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, theophyline and chromones, oral corticosteroids and β2 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mohamad Bagher Montazeri
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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

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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