Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efficacy of Plantago major syrup on severity of cough in acute bronchitis

Protocol summary

Study aim
investigating the therapeutic effect of Plantago major on the severity of cough in acute bronchitis

Design
randomized Placebo-controlled clinical trial (Phase 3), in 80 patients with a clinical diagnosis of acute bronchitis. Randomization is done using permuted block randomization. The drugs are studied by Sanabel Daru Co. in two categories (drugs and placebo) and coded by a statistician and placed in blocks of 4 (containing 2 from each group). And given blindly to the researcher. Patients are placed in one of the Plantago major syrup or Placebo groups for 10 days.

Settings and conduct
80 patients with symptoms of acute bronchitis who are referred to the Infectious Diseases Clinic of Ayatollah Rouhani Hospital in Babol evaluate with the BSS (Bronchitis Severity Scale) questionnaire. After assessing the inclusion and exclusion criteria, patients are randomly assigned to one of the Plantago major syrup or Placebo groups and will be evaluated in 5 and 10 days of consuming the medications.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 20-75 years old; BSS equal to or greater than 5 on the first visit; Symptoms begin less than two weeks before the study begins Exclusion criteria: Pregnant or lactating women; Patients who received specific medications within 4 weeks of study; Patients who have taken a cough and sputum medication for the week before the study or have a history of a specific illness.

Intervention groups
Intervention: plantago major and placebo 10 ccs in three times, for 10 days

Main outcome variables
Bronchitis Severity Scale, the severity of cough, quality of life in acute cough (Leicester Cough Questionnaire)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046009N2**
Registration date: **2020-07-12, 1399/04/22**
Registration timing: **prospective**

Last update: **2020-07-12, 1399/04/22**
Update count: **0**

Registration date
2020-07-12, 1399/04/22

Registrant information

Name
Seyyed Ali Mozaffarpur

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3219 4728

Email address
dr.mozaffarpur@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-05, 1399/05/15

Expected recruitment end date
2021-01-18, 1399/10/29

Actual recruitment start date
2020-08-05, 1399/05/15

Actual recruitment end date
2021-03-19, 1399/12/29

Trial completion date
2021-04-20, 1400/01/31

Scientific title

The efficacy of Plantago major syrup on severity of cough in acute bronchitis

Public title
effect of plantago major on severity of cought
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age between 20 t0 75 years old acute cough clinical diagnosis of acute bronchitis
Exclusion criteria:
Pregnant or lactating women Patients who took a cough and sputum medication for one week before the study History of respiratory disease such as chronic bronchitis, bronchiectasis, asthma-pneumonia, cystic fibrosis, lung cancers or active pulmonary tuberculosis Kidney or liver failure Genetic diseases such as galactose intolerance or lactose intolerance History or presence of cardiovascular disease, neurological disease, metabolic disease or mental disorders. Hematologic disease or malignant tumor (unless recurrent within 5 years) A history of alcohol or substance abuse
Age
From **20 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **40**
Based on similar studies to indicate a 25% difference in cough remission, the sample size was calculated to be 36% for each group, taking into account the first type error of 5% and the power of 90%. Considering the possibility of a 10% drop, the final sample size in each group was 40 individuals. (Total 80 people)
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Drugs in two categories (drug and placebo) are made by Sanabel Daru Co. and sent to the statistician. Randomization is done using permuted blocks randomization. The size of the blocks is considered 4. All possible combinations are determined from a sequence of 4 of the two drugs (6 combinations), and then their sequence is determined using a table of random numbers. The statistician encodes them and gives them to the researcher blind. Unlock codes will be done after the end of the study. In case of side effects, the drug code will be unlocked.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo syrup and medicine will be prepared in the same form, label, taste, and odor, by the Sanabel DaruCo. The only one who knows the identity of the syrups is the biostatistician of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Babol, Sargor Ghasemi avenue, Babol University of Medical science
City
Babol
Province
Mazandaran
Postal code
4718647745
Approval date
2020-01-19, 1398/10/29
Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.342

Health conditions studied

1

Description of health condition studied
Brunchit
ICD-10 code
J21
ICD-10 code description
Acute bronchiolitis

Primary outcomes

1

Description
severity of acute bronchitis
Timepoint
Assessing patients at the first visit (before starting the study), on the fifth day and on the tenth day after starting treatment
Method of measurement
Bronchitis Severity Score (BSS) questionnaire

Secondary outcomes

1

Description
quality of life for acute cough
Timepoint
Before starting treatment, after the end of treatment
Method of measurement
Standard Quality of Life Questionnaire for Acute Cough (Leicester Cough Questionnaire)

2

Description
severity of cough
Timepoint
Assessing patients at the first visit (before starting the study), on the fifth day and on the tenth day after starting treatment
Method of measurement
cough evaluating questionnaire based on Visual Analog Scales

Intervention groups

1

Description
Intervention group: Plantago major syrup containing extract of the seed of Plantago major, made by Sanabel Daru Company is used. Syrups are given to the patient on a weekly basis in 300 cc pets. The patient takes 30 ccs orally (10 ccs three times every 8 hours) daily for 10 days.
Category
Treatment - Drugs

2

Description
Control group: Placebo syrups with the same taste, color, smell, shape and label of the Plantago major syrup will be made by Sanabel Daru Company. Syrups are given to the patient on a weekly basis in 300 cc pets. The patient takes 30 cc orally (10 cc in three times, every 8 hours) daily for 10 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roohani Hospital
Full name of responsible person
Seyyed Ali Mozaffarpur
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Babol, Ganjafrooz Ave, Near Babol University of Medical Science. Roohani Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Babol university of medical sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Seyyed Ali Mozaffarpur

Position
Associate professor
Latest degree
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Other areas of specialty/work
Traditional Medicine
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
the primary outcome measure
When the data will become available and for how long
starting after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
systematic review or meta-analysis
From where data/document is obtainable
email to seyyedali1357@gmail.com
What processes are involved for a request to access data/document
email to seyyedali1357@gmail.com
Comments