

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+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 cough

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

age between 20 to 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

##### Street address

Babol, Ganjafrooz Ave, Near Babol University of Medical Science. Roohani Hospital

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+98 11 3219 4728

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Seyyedali1357@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Reza Ghadimi

##### Street address

Babol, Sargord Ghasemi Ave, Babol University of Medical Science

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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**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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Babol. Ganj afrooz. Babol university of Medical Science. School of Persian Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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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**