Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Clinical Efficacy and Safety of Pelargonium Sidoides EPs 7630 Root Extract in Symptomatic Treatment of Acute viral Bronchitis in Children 6 Months to 6 Years

Protocol summary

Study aim

To evaluate the clinical efficacy of Pelargonium sidoides root extract (EPs 7630) in the treatment of cough in acute viral bronchitis among children aged 6 months to 6 years attending the Children's Medical Center Hospital.

Design

Blinding will be performed in a double-blind manner using identical drug and placebo formulations. Participants will be randomly assigned to groups using a block randomization method,

Settings and conduct

his study will be conducted as a randomized, triple-blind clinical trial (patient, investigator, and data analyst) over a period of six months on patients aged 6 months to 6 years presenting with symptoms of acute viral bronchitis to the emergency outpatient clinic of the Children's Medical Center Hospita

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged 6 months to 6 years without underlying conditions diagnosed with acute bronchitis. Onset of symptoms less than 48 hours before enrollment (Symptom severity: Bronchitis Severity Score (BSS) ≤ 5 Exclusion Criteria: Use of antibiotics within the past two weeks. Use antihistamines. Use of cold medications Non-compliance with follow-up visi

Intervention groups

n the symptomatic treatment of acute viral bronchitis in children aged 6 months to 6 The initial visit will be conducted at the time of enrollment, and the final follow-up visit will take place on day seven. The Bronchitis Severity Score (BSS) is used to assess disease severity based on the patient's clinical symptoms and includes cough, pulmonary rales on auscultation, and dyspnea. The presence and severity of each symptom are evaluated using a five-point scale as follows: 0 = absent, 1 = mild, 2 = moderate, 3 = severe, and 4 = very severe.

Main outcome variables

Does Pelargonium sidoides root extract (EPs 7630) affect the duration of fever in children aged 6 months to 6 years attending the Children's Medical Center Hospital?

General information

Reason for update

Acronym

Bronchitis Severity Scale (BSS), clinical outcome, acute bronchitis, Pelargonium Sidoides EPs ۷۶۳۰ Root extract

IRCT registration information

IRCT registration number: **IRCT20250926067363N1**
Registration date: **2026-04-30, 1405/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-30, 1405/02/10**
Update count: **0**

Registration date

2026-04-30, 1405/02/10

Registrant information

Name
rohola shirzadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6147 9000
Email address
shirzadi123@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2026-06-20, 1405/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Clinical Efficacy and Safety of Pelargonium Sidoides EPs 7630 Root Extract in Symptomatic Treatment of Acute viral Bronchitis in Children 6 Months to 6 Years

Public title

Evaluation of Clinical Efficacy and Safety of Pelargonium Sidoides EPs 7630 Root Extract in Symptomatic Treatment of Acute viral Bronchitis in Children 6 Months to 6 Years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

“Symptoms with a Bronchitis Severity Score (BSS) ≤ 5”“(BSS) ≥ ۵” n children aged 6 months to 6 years without underlying conditions who develop bronchitis, the severity is typically mild to moderat Acute onset of symptoms less than 48 hours before enrollment (first visit).”

Exclusion criteria:

“Use of antibiotics within the past two week “Use of other medications such as antihistamines Irregular use of medication Lack of compliance with follow-up visits old medications or other oral drugs that may interfere with the improvement of the patient’s symptom

Age

From **6 months** old to **6 years** old

Gender

Both

Phase

4

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

the intervention and control groups, using SPSS software. The random sequence will be generated using the RV.UNIFORM function in SPSS, and participants will be selected systematically at intervals of 5 from the main list. The randomization sequence will be kept in sealed envelopes and will only be revealed after data analysis to determine group allocation. In this study, children will be evaluated by a pediatric specialist at two time points: an initial visit upon enrollment and a follow-up visit on day 7.

Blinding (investigator's opinion)

Triple blinded

Blinding description

identical. A double-blind approach is used, with the drugs labeled as A and B. The actual identity of each code (drug or placebo) will only be revealed after data analysis.

Placebo

Used

Assignment

Single

Other design features

defined as the primary outcome. To evaluate the safety of EPs 7630 treatment in children aged 6 months to 1 year, adverse events will be assessed at each visit.Integrative Medicine Outcome Scale (IMOS): A 5-point Likert verbal scale used to assess the patient’s overall health status.Integrative Medicine Patient Satisfaction Scale (IMPSS): A 5-point Likert verbal scale used to assess the level of satisfaction with the treatmen

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran University of Medical Sciences children medical cener

Street address

“No. 62, Dr. Gharib Street, Children’s Medical Center

City

tehran

Province

Tehran

Postal code

1419733151

Approval date

2025-08-01, 1404/05/10

Ethics committee reference number

IR.TUMS.CHMC.REC.1404.145

Health conditions studied

1

Description of health condition studied

Acute bronchitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluation of Clinical Efficacy and Safety of Pelargonium Sidoides EPs ۷۶۳۰ Root Extract in Symptomatic Treatment of Acute viral Bronchitis in Children ۶ Months to ۶ Years

Timepoint

“Day 1 and Day7

Method of measurement

“The Bronchitis Severity Score (BSS) is assessed based on the patient’s clinical symptoms, including cough, pulmonary rales on auscultation, and dyspnea. Each symptom is evaluated using a 5-point scale: 0 = absent, 1 = mild, 2 = moderate, 3 = severe, and 4 = very severe. The individual scores are then summed to produce a total score ranging from 0 to 1

Secondary outcomes

1

Description

the change in the total BSS score between baseline (Day 1) and Day 7 has been defined as the primary outcome. To assess the safety of EPs 7630 treatment in children aged 6

Timepoint

“Day 1 and Day 7

Method of measurement

pulmonary rales on auscultation, and dyspnea. Each symptom is evaluated using a 5-point scale: 0 = absent, 1 = mild, 2 = moderate, 3 = severe, and 4 = very severe. The scores are then summed to generate a total score ranging from 0 to 12

Intervention groups

1

Description

Intervention Group: Implementation Method“This study will be conducted as a randomized, triple-blind clinical trial (patient, investigator, and data analyst) over a period of six months on outpatients aged 6 months to 6 years presenting with symptoms of acute bronchitis to the Emergency Clinic of the Children’s Medical Center Hospital. Participants will be randomly assigned to two groups and will receive either Pelargonium sidoides root extract (EPs 7630) or placebo.For the intervention group:Infants aged 6 months to 1 year will receive Pelarzhin Kids drops (containing 136.5 mg standardized Pelargonium extract) at a dose of 20 drops (1 mL), three times daily.Children aged 1 to 6 years will receive 2.5 mL of Pelarzhin Kids syrup (containing Pelargonium sidoides root extract and honey) three times daily (morning, noon, and evening).Both formulations are manufactured by Pars Gita Darou Pharmaceutical Company

Category

Treatment - Other

2

Description

the second group will also receive placebo treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

children medical center

Full name of responsible person

Rohola Shirzadi

Street address

No. 62, Dr. Gharib Street, Children’s Medical Center.

City

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Email

shirzadi123@yahoo.com

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Rohola Shirzadi - ramin kordi

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Web page address

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Grant name

“From the research budget of the faculty/research center

Grant code / Reference number

۱۴۰۴-۱-۳۶۵-۷۵۱۹۱

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Rohola shirzadi

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after de-identification of individuals.”

When the data will become available and for how long

From publication until 6 months thereafter.”

To whom data/document is available

he data will be available only to researchers affiliated with academic or scientific

Under which criteria data/document could be used

faculty members of the university.

From where data/document is obtainable

“They should contact via the email address: shirzadi123@yahoo.com

What processes are involved for a request to access

data/document	“It will be sent within one week after identity verification
Comments	