

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effect of rotarin drug on the symptoms and severity of sore throat in patients with bacterial and allergic sore throats compared with placebo

Protocol summary

Study aim

Determination of the effect of Rotarin drug on the symptoms and severity of sore throat in patients with bacterial and allergic sore throats compared with placebo

Design

Clinical trial study with control group, with parallel groups, double-blind, randomized by simple randomization method using random numbers table, 80 patients, phase 3

Settings and conduct

In this study, the samples were selected from patients with sore throat who went to the private doctor's office with the Convenience Sampling method and individuals were divided into groups by simple randomization. If patients wish to participate in this research, first the goals and method of conducting the study for patients were explained and then, a written consent was obtained from all volunteer patients. At the beginning of the visit, after recording the severity of the patient's sore throat and completing the quality of life questionnaire, patients were asked to mix 2 sachets of Rotarin in lukewarm water daily for 7 days and drink it in the morning and evening. After 7 days, visit again to record the severity of pain and quality of life questionnaire for each patient. In addition, all patients were asked to take the medication prescribed by their doctor in accordance with the instructions, in addition to taking this herbal medicine.

Participants/Inclusion and exclusion criteria

inclusion criteria: Aged 18-65 years; diagnosis of bacterial and allergic diseases by a physician. Exclusion criteria: Patients' reluctance to participate in the study; Pregnancy and lactation.

Intervention groups

rotarian group, placebo group

Main outcome variables

The severity of the pain; Daily activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N3**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

2017-10-23, 1396/08/01

Actual recruitment end date

2018-02-09, 1396/11/20

Trial completion date

2018-02-20, 1396/12/01

Scientific title

Investigation of the effect of rotarin drug on the symptoms and severity of sore throat in patients with bacterial and allergic sore throats compared with placebo

Public title

Rotarin effect on sore throat in patients with bacterial and allergic sore throats

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of bacterial and allergic diseases by a physician Aged 18-65 years

Exclusion criteria:

Pregnancy and lactation Patients' reluctance to participate in the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients were assigned to two groups of Rotarin and placebo based on a Simple randomization method. This means that all participants had an equal chance of being in each group. The first step is to create a random sequence. For this purpose, we used a table of random numbers. From the beginning, it was decided to go down to read the numbers in the table of random numbers, after selecting the starting point. We then determined that even numbers were assigned to the intervention group and individual numbers were assigned to the placebo group. Due to the fact that when using simple randomization methods, especially in low sample size, it is possible that the two groups do not equal at the same time, so if a group reaches its sample size earlier, then we must ignore the relevant figures, and complete the opposite group. One of the project's colleagues put his finger on a point in the table with his eyes closed, and then, as scheduled, moved down and wrote down the numbers until they reached the sample size in both groups. Each number, depending on whether they were even or odd, represented a group to which we assigned code A (intervention) and B (placebo). With this method, we had a specific sequence of 80 codes A and B at the end, indicating that the first to eightieth person to be included in the study should belong to each group. We wrote the code on a piece of paper in order and put it in an envelope, to use it during sampling. Thus, after reviewing the entry criteria and, if the client wishes, we

entered each person into the groups according to our pre-determined list.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti medical university

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1172

Health conditions studied

1

Description of health condition studied

Patients with bacterial or allergic sore throat

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The severity of the pain

Timepoint

baseline and end of study

Method of measurement

Quality of Life Questionnaire

2

Description

The effect of disease severity on daily activity

Timepoint

baseline and end of study

Method of measurement
Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rotarin (a combination of Plantago ovata forsk, plantago major, quince seed, basil seed and Merv egg), for 7 days, daily 2 sachets of Rotarin mixed with lukewarm water, morning and evening

Category

Treatment - Drugs

2

Description

Control group: placebo, for 7 days, daily 2 sachets of placebo mixed with lukewarm water, morning and evening

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
private clinic

Full name of responsible person
Soodeh Razeghi Jahromi

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No. 46, West Arghavan St., Farahzadi Blv., Qods Town

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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

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Soodeh Razghei Jahromi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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