

# 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)

##### Phone

+98 21 6634 8500

##### Email address

razeghi@sina.tums.ac.ir

##### 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

**Street address**  
No. 46, West Arghavan St., Farahzadi Blv., Qods Town

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1981619573

**Phone**  
+98 21 22357

**Email**  
soodehrazeghi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Soodeh Razeghi Jahromi

**Street address**  
No. 46, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**  
1981619573

**Phone**  
+98 21 22357

**Email**  
soodehrazeghi@gmail.com

#### 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

**Street address**  
No. 46, West Arghavan St., Farahzadi Blv., Qods Town

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1981619573

**Phone**  
+98 21 22357

**Email**  
soodehrazeghi@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razeghi Jahromi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

4741-19395

**Phone**

+98 21 22357

**Email**

soodehrazeghi@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razeghi Jahromi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 22357

**Email**

soodehrazeghi@gmail.com

**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