

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The clinical efficacy of *Platanus orientalis* L. distillate, as nasal drop, in allergic rhinitis- a pilot, randomized, double-blind, placebo-controlled clinical trial

#### Protocol summary

##### Study aim

Observing the efficacy of *Platanus orientalis* L. distillate in allergic rhinitis symptoms

##### Design

A clinical pilot study, randomized, placebo-controlled, double blind Sample size: 30 patients Permuted block randomization was applied.

##### Settings and conduct

Thirty patients are selected randomly among the patients referred to Emam Reza Clinic, Shiraz. They are asked to use the drop 4 times a day for one month and record daily symptoms. The probable side effects are recorded. Local and systemic corticosteroids are prohibited. Clinical symptoms are scored.

##### Participants/Inclusion and exclusion criteria

Thirty patients. Inclusion criteria: Patients aged 18-65 years Obtaining the informed consent Fulfillment of allergic rhinitis diagnostic criteria and the history of allergic rhinitis for at least two consecutive years Exclusion criteria: Pregnancy Breast feeding Females at age of fertility with no particular pregnancy prevention method Systemic corticosteroid therapy in the past three months Local corticosteroid therapy in the past fifteen days

##### Intervention groups

Intervention group: (Test medication: *Platanus orientalis* L. distillate) Control group: (Placebo: Sterilized distilled water)

##### Main outcome variables

1- Allergic rhinitis symptom score (nose, eyes, respiratory), 2- Quality of life score (regular activities, recreational activities, sleep)

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20100218003361N2**

Registration date: **2018-12-30, 1397/10/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-30, 1397/10/09**

Update count: **0**

#### Registration date

2018-12-30, 1397/10/09

#### Registrant information

##### Name

Soheila Alyasin

##### Name of organization / entity

Shiraz University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4298

##### Email address

alyasins@sums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-12-19, 1397/09/28

#### Expected recruitment end date

2019-05-19, 1398/02/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The clinical efficacy of *Platanus orientalis* L. distillate, as

nasal drop, in allergic rhinitis- a pilot, randomized, double-blind, placebo-controlled clinical trial

#### Public title

Evaluation of Platanus orientalis L. distillate effects on allergic rhinitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients aged 18-65 years Obtaining the informed consent Fulfillment of allergic rhinitis diagnostic criteria and the history of allergic rhinitis for at least two consecutive years

##### Exclusion criteria:

Systemic corticosteroid therapy in the past three months  
Local corticosteroid therapy in the past fifteen days  
Pregnancy Breast feeding Females at age of fertility with no particular pregnancy prevention method

#### Age

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

#### Gender

Both

#### Phase

0

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Permuted block randomization method was applied. Random allocation software was used. Equal block sizes were used and based on the sample size (30) and two treatment groups, eight permuted blocks of four were produced. In this method, the number of test and control cases is equal in each block. All of the randomized permuted blocks of 4 are noted and in each step one of them is selected randomly.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Subjects and study personnel (including principal investigator) were blinded in this study. Nasal drops in placebo and test group were prepared in identical packages (with a number based on the randomization method) by research center personnel who were not associated with the subject's clinical management, data collection and analysis, to ensure blinding. Because of the similar packaging, placebo and test drops were not distinguishable.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Zand street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

#### Approval date

2018-10-27, 1397/08/05

#### Ethics committee reference number

IR.SUMS.REC.1397.718

## Health conditions studied

### 1

#### Description of health condition studied

Allergic rhinitis

#### ICD-10 code

J30.9

#### ICD-10 code description

Allergic rhinitis, unspecified

## Primary outcomes

### 1

#### Description

Allergic rhinitis symptom score (nose, eyes, respiratory)

#### Timepoint

Daily

#### Method of measurement

Filling the daily symptom questionnaire and symptom scores by the patient

### 2

#### Description

Comparing the daily mean scores of allergic rhinitis

#### Timepoint

Day 1- Day 30

#### Method of measurement

Statistical analyses

### 3

#### Description

Quality of life score (regular activities, recreational activities, sleep)

## Timepoint

At enrollment, at days 14 and 30

## Method of measurement

Quality of life scoring in quality of life questionnaire

## 4

### Description

Observing the variations in the severity of allergic rhinitis symptoms

### Timepoint

Day 30

### Method of measurement

Clinician evaluations

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Platanus Orientalis L. distillate, prepared as nasal drop. It is applied 4 times a day for one month. Distillate is prepared in research center and is filled in the drop containers following filtration.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: distilled water

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Clinic, Shiraz University of Medical Sciences

##### Full name of responsible person

Soheila Alyasin

##### Street address

Zand street, Namazi square

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Soheila Alyasin

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Soheila Alyasin

##### Position

Associate Professor of Pediatrics

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatrics

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Department of Pediatrics, Namazee Hospital, Shiraz University of Medical Sciences, Shiraz, Iran

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## Person responsible for scientific inquiries

### Contact

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Shiraz University of Medical Sciences  
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Dr.Soheila Alyasin  
**Position**  
Associate Professor of Pediatrics, Pediatric Immunology and Allergy specialist  
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Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

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Associate Professor of Pediatrics, Pediatric Immunology and Allergy specialist

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Subspecialist

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

**Informed Consent Form**  
Undecided - It is not yet known if there will be 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**  
Not applicable

**Data Dictionary**  
Not applicable