

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

City

Shiraz

Province

Fars

Postal code

71348714737

Phone

+98 71 3212 7001

Email

emamreza@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Soheila Alyasin

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

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

Street address

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

City

Shiraz

Province

Fars

Postal code

-

Phone
+98 36122268
Email
alyasins@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Soheila Alyasin
Position
Associate Professor of Pediatrics, Pediatric Immunology and Allergy specialist
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Department of Pediatrics, Namazee Hospital, Shiraz
University of Medical Sciences, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
-
Phone
+98 71 3612 2268
Email
alyasins@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Dr.Soheila Alyasin

Position
Associate Professor of Pediatrics, Pediatric Immunology and Allergy specialist

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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

City
Shiraz

Province
Fars

Postal code
-

Phone
+98 36122268

Email
alyasins@sums.ac.ir

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