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 Sience
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

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
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 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

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
-
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+98 36122268
Email
alyasins@sums.ac.ir

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Analytic Code
Not applicable
Data Dictionary
Not applicable