Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

: A randomized, tripple blind, controlled, clinical trial effect of simple zofa (hyssopus officinalis) syrup on persistant asthma

Protocol summary

Study aim

effect of simple hyssop syrup on asthmatic patients

Design

In this research, 60 asthmatic eligible patients were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

Patients known by plan notifications (playing in the Shiraz government and nongovernment care centers) will come to Hakim Emaddin Shirazi clinic. They will visit by an internist and persistant asthmatic patients will be referd to traditional medicine resident. Eligible patients refer to spirometry part of shahid faghihi hospital after informed consent signing. Then they refer to Hakim Emaddin Shirazi clinic for receiving drug, primary outcome measures registration(spirometry indicator: FEV1 , FEV1 /FVC , EPR3 asthma treatment investigation score(7th index), ACT score(6th index)). Researcher calls all the patients in second week to prevent missing and ask them about drug consumption and probably side effects. patients will be visited after 4 weeks in Hakim Emaddin Shirazi clinic and will be refered to shahid faghihi hospital for final spirometry. Then they refer to Hakim Emaddin Shirazi clinic for secondary outcome measures registration(FEV1 , FEV1 /FVC , EPR3 asthma treatment investigation score(7th index), ACT score(6th index)). Completing ethic form(8th index), demographic information form(first index), lung nature form(3th and 4th index), receiving drug consumption checklist(5th index) and recording of wheezing intensity will be done at the first visit. Completing lung nature form and recording of wheezing intensity will be done at the second visit too. Wheezing intensity definition(according to history and physical exam): sever: difficult breathing at rest, expiration wheezing and generalized rhonchi(1 score), moderate: non difficult breathing at rest, expiration wheezing and generalized rhonchi(2 score), mild: prolonged expiration,scattered rhonchi(3 score). ACT form will be completed after 8 weeks too via calling.Returning to clinic will be advised to all patients if symptom get worst or side effect appear. Intervention group patients will consume oral intervention drug (hyssop syrup) twice a day(fasting and bed time with 6.5 gram hyssop in each time) for 4 weeks(consumption volume will determine after drug production). Control group patients will consume oral placebo (candy syrup) twice a day(as the same as Intervention group patients consumption). patients will be advised to eat drug with warm water for prevention of constipation. drug will be added to their common treatment. if side effect happen, drug will be interrupted and necessary cares will be done. Participants,care provider, outcome assessor, investigator and data analyzer will be blind. In this study, Care provider, Outcome assessor and Investigator are the same. Randomization and encoding will be done by pharmacist of Ahura company. Appearance of drug and placebo will be the same. They will be encode by two different digital code. Only researcher can deciphers each battle according to early form of randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: older than 18 years old patients, confirm of disease by internist. diagnosis criteria: according to NAEP EPR3 criteria for persistent asthma disease: FEV1: 60-80%; Exclusion criteria: history of allergy to plant of mint family, dissatisfaction of treatment in each stage, side effect development through treatment, theophylline cosumption, diabetic patients, convulsion history, pregnant patients, patient that need to hospitalize, exacerbation at beginning of study, smokers, disability in statement of symptom intensity

Intervention groups

Intervention group patients will consume oral intervention drug (hyssop syrup) twice a day(fasting and bed time with 6.5 gram hyssop in each time) for 4 weeks(consumption volume will determine after drug production). Control group patients will consume oral placebo (candy syrup) twice a day(as the same as Intervention group patients consumption). patients will

be advised to eat drug with warm water for prevention of constipation. drug will be added to their common treatment. It means that according to EPR3 treatment protocol, at first line, long-acting beta-agonist (salmeterol) and inhaled steroid are prescribed to all patients(short-acting beta-agonist (salbutamol) is advised to all patients if necessary.

Main outcome variables

spirometry indicator: FEV1 , FEV1 /FVC ; EPR3 asthma treatment investigation score(7th index); ACT score(6th index).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110811007297N5**
Registration date: **2018-04-04, 1397/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-04, 1397/01/15**
Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

Mojtaba Heydari

Name of organization / entity

Shiraz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 71 1235 7679

Email address

mheydari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: A randomized, tripple blind, controlled, clinical trial effect of simple zofa (hyssopus officinalis) syrup on persistant asthma

Public title

effect of simple zofa (hyssopus officinalis) syrup on persistant asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

older than 18 years old patients confirm of disease by internist. diagnosis criteria: acording to NAEP EPR3 criteria for persistant asthma disease: FEV1: 60-80%

Exclusion criteria:

history of allergy to plant of mint family dissatisfaction of treatment in each stage side effect development through treatment theophylline cosumption diabetic patients convulsion history pregnant patients patienta that need to hospitalize Exacerbation at beginning of study smokers diability in statement of symptom intensity

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified patients divide into tow groups of thirty. Only researcher can deciphers each battle according to early form of randomization.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Paticipants,Care provider, Outcome assessor, Investigator and Data analyser wont know encoding. In this study, Care provider, Outcome assessor and Investigator are the same. Randomization and encoding will be done by pharmacist of Ahura company. Appearance of drug and placebo will be the same. They will be encode by two different digital code. Only researcher can deciphers each battle according to early form of randomization.

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 school
Street address
Zand street, Emam Hosein square, medical school, department number 2, 8th floor, ethic committee
City
Shiraz
Province
Fars
Postal code
713484594
Approval date
2017-11-13, 1396/08/22
Ethics committee reference number
IR.SUMS.MED.REC.1396.75

Health conditions studied

1

Description of health condition studied
persistent asthma
ICD-10 code
J45.0
ICD-10 code description
Predominantly allergic asthma

Primary outcomes

1

Description
spirometry indicator: FEV1 and FEV1 /FVC
Timepoint
at the first of the study(before intervention) and 4 weeks after intervention
Method of measurement
spirometry set

2

Description
asthma treatment investigation score(The Expert Panel Report 3 (EPR 3))
Timepoint
at the first of the study(before intervention) and 4 weeks after intervention
Method of measurement
asthma treatment investigation questionnaire (The Expert Panel Report 3 (EPR 3))

3

Description
asthma control test(ACT) score
Timepoint
at the first of the study(before intervention) , 4 weeks and 8 week after intervention
Method of measurement
asthma control test questionnaire(ACT)

Secondary outcomes

1

Description
Wheezing intensity determination
Timepoint
At the first of the study(before intervention) and 4 weeks after intervention
Method of measurement
History and physical exam with stethoscope

2

Description
Lung dystemperament
Timepoint
At the first of the study(before intervention) and 4 weeks after intervention
Method of measurement
Primary questionnaire of lung dystemperament investigation in terms of warm and cold and primary questionnaire of lung dystemperament investigation in terms of wet and drought

Intervention groups

1

Description
Intervention group: En Intervention group patients will consume oral intervention drug (hyssop syrup) twice a day(fasting and bed time with 6.5 gram hyssop in each time) for 4 weeks(consumption volume will determine after drug production). Patients will be advised to eat drug with warm water for prevention of constipation. Drug will be added to their common treatment. It means that according to EPR3 treatment protocol, at first line, long-acting beta-agonist (salmeterol) and inhaled steroid are prescribed to all patients(short-acting beta-agonist (salbutamol) is advised to all patients if necessary. Drug and placebo will produce by Ahura company. Drug component: floral branch of Hyssopus officinalis L . Place of plant purchase: Aramis grocery, Isfahan gate, in front of the Ali Ibn Abitaleb mosque, Dr. Ansarifard. Documentation of plant: Matching of bought plant with Hyssopus officinalis L. was done by Botanist School of Pharmacy, Shiraz and were maintained by PM984 code at her barium of that school. Drug production: Candy syrup will produce after Zufa extract by Ahura company. Placebo production: Candy syrup will produce by Ahura company too. GC-mass analysis of Zufa essence was done by phytochemistry group of Shiraz medical university. Identity was done according to Adamz book.
Category
Treatment - Drugs

2

Description
Control group: Control group patients will consume oral placebo (candy syrup) twice a day(as the same as

Intervention group patients consumption). Patients will be advised to eat drug with warm water for prevention of constipation. Drug will be added to their common treatment. It means that according to EPR3 treatment protocol, at first line, long-acting beta-agonist (salmeterol) and inhaled steroid are prescribed to all patients(short-acting beta-agonist (salbutamol) is advised to all patients if necessary. Drug and placebo will produce by Ahura company

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hakim Emaddin Shirazi clinic

Full name of responsible person
Fatemeh Amini

Street address
Zand street, Flestin avenue, between Hedayat and Hakimi street, next to3th alley, plaque number 49

City
Shiraz

Province
Fars

Postal code
7134733519

Phone
+98 71 3234 0461

Fax

Email
su.azadeh.2005@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Seyed Basir Hashemi

Street address
Zand Av, Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
14336 - 71348

Phone
+98 71 3212 2722

Email
vcrdep@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 Amir Mohammad Jaladat

Position
MD,Ph.D Assistant professor in Traditional Persian Medicine

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Province
Fars

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7134845794

Phone
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Email
drjaladat@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Leila Hoseini

Position
Assistant professor in Traditional Persian Medicine

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Amini
Position
MD, Ph.D student in Traditional Persian Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
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Shiraz
Province
Fars
Postal code
71348445794
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+98 71 3234 5145
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su.azadeh.2005@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
outcome major information including: fev1/fvc pre and post study
When the data will become available and for how long
6 months after results pressing
To whom data/document is available
scientific reaserchers
Under which criteria data/document could be used
After publication of the extracted article of the clinical trial
From where data/document is obtainable
su.azadeh.2005@gmail.com
What processes are involved for a request to access data/document
Sending the request via the email
Comments