Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the effectiveness of herbal products of Myrtus communis compared with Clindamycin 1% in reducing symptoms of Acne Vulgaris ,mild to moderate

Protocol summary

Study aim

The purpose of this study is to determine the anti acne effect of Myrtus commmunis formulation versus clindamycine 1% . the practical purpose of it is to introduce an effective drug with low side effects for treatment of acne based on iranian medicine.

Design

The study population are selected from the patients who have inclusion criteria and referred to traditional medicine clinic of Ahmadiyeh, traditional medicine clinic of Behesht or Skin and Stem Cell Research Center , after filling consent form. The sample size is 55 people. The study will be designed in a bilateral form and the the Myrtus communis formulation will be applied on one side of the face and the clindamycin1% will be applied on the other side for three months. The number and severity of skin lesions will be counted and evaluated within the defined periods of the treatment (at the end of the sixth, twelfth and sixteenth week of the treatment) which is expected to be decreased

Settings and conduct

The study will be designed in split face. Myrtus communis formulation will be applied on one side of the face and the clindamycin1% will be applied on the other side for 12 weeks. The number and acne severity index will be counted and evaluated within the defined periods of the treatment (at the end of the sixth, twelfth and sixteenth week of the treatment). The place of study is in the traditional medicine clinic of Ahmadiyeh and Behesht or Skin and Stem Cell Research Center.

Participants/Inclusion and exclusion criteria

12–45 years old, facial acne vulgaris, mild to moderate

Intervention groups

Intervention group: Myrtus communis topical formulation two times a day in one side of the face for 12 weeks
Control group: Clindamycin1% solution two times a day in another side of the face for 12 weeks

Main outcome variables

number and acne severity index side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037581N1**
Registration date: **2018-01-02, 1396/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-05, 1398/06/14**
Update count: **3**

Registration date

2018-01-02, 1396/10/12

Registrant information

Name

Mahboobeh Salmanian haji agha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 9724

Email address

salmanian.m@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

2017-12-06, 1396/09/15

Actual recruitment end date

2019-07-04, 1398/04/13

Trial completion date

2019-07-04, 1398/04/13

Scientific title

Evaluation of the effectiveness of herbal products of Myrtus communis compared with Clindamycin 1% in reducing symptoms of Acne Vulgaris ,mild to moderate

Public title

Myrtus communis effect in acne treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being 12–45 years old Facial acne vulgaris, mild to moderate (Having 20-140 total lesion count, 10-90 noninflammatory facial lesions, 10-50 inflammatory lesions, without facial nodular cystic lesion)

Exclusion criteria:

Have a skin disease that might interfere with the diagnosis or evaluation of their skin lesions Severe systemic disease Pregnant and lactating women Use of topical anti acne therapy two months before or during the study Use of oral retinoids six months before the study known allergy or sensitivity to any of the study medications or their components Incidence of side effects Unwillingness to continue this study Unable to follow up the patient regularly

Age

From **12 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **55**
More than 1 sample in each individual
Number of samples in each individual: **2**
right and left side of the face
Actual sample size reached: **48**
More than 1 sample in each individual
Actual sample size in each individual: **2**
right and left side of the face

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients will receive two drug containers with the same shape and size but different content. each patient instructed to use antiacne1 on right side of the face and antiacne 2 on the left side. the patiant, the physician who will examine the patients and appraiser of them will not be aware of the contents of the drug containers.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-10-08, 1396/07/16

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9321309010

Health conditions studied

1

Description of health condition studied

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Total lesion Count

Timepoint

At the beginning of the study and at the end of the sixth, twelfth and sixteenth week of the study

Method of measurement

Counting the Comedones, Papules and Pustules

2

Description

Severity of Acne

Timepoint

At the beginning of the study and at the end of the sixth, twelfth and sixteenth week of the study

Method of measurement

Acne Severity Index

3

Description
Speed of onset of treatment(The mean time to a 50% reduction in acne lesion) in every half of the face
Timepoint
At the end of the sixth and twelfth week
Method of measurement
Index of Severity of Acne=ASI Total lesion Count = TLC

4

Description
Recurrence
Timepoint
4 weeks after treatment
Method of measurement
Index of Severity of Acne=ASI Total lesion Count = TLC

Secondary outcomes

1

Description
Side effects
Timepoint
At the end of the sixth, twelfth and sixteenth week of the study
Method of measurement
Common terminology criteria for Adverse Evently v4.02009

2

Description
Skin erythema
Timepoint
Before intervention and 16 weeks after the beginning of intervention
Method of measurement
Mexameter

3

Description
Skin hydration
Timepoint
At the beginning of the study and the end of sixteenth week of the study
Method of measurement
Corneometer

4

Description
Change in sebum production
Timepoint
At the beginning of the study and the end of sixteenth week of the study
Method of measurement
Sebumeter

5

Description
Acne lesion and presence of Propionibacterium acnes bacteria
Timepoint
At the beginning of the study and the end of sixteenth week of the study
Method of measurement
Visiopor

6

Description
Melanin
Timepoint
At the beginning of the study and the end of sixteenth week of the study
Method of measurement
Mexameter

7

Description
Patient satisfaction
Timepoint
At the end of twelfth week
Method of measurement
questionnaire

8

Description
Evaluation of drug tolerance by the patient on each side of the face(burning, pruritus)
Timepoint
At the end of the sixth, twelfth and sixteenth week of the study
Method of measurement
questionnaire

9

Description
Evaluation of drug tolerance by the physician on each side of the face(erythema, dryness, peeling)
Timepoint
At the end of the sixth, twelfth and sixteenth week of the study
Method of measurement
examination

Intervention groups

1

Description
Intervention group: the Myrtus communis topical formulation will be applied on one side of the face two times a day for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: the clindamycin1% will be applied on the other side of the face for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadieh traditionale clinic
Full name of responsible person
Lila Shirbeigi
Street address
North Sarparast Street, Palestine Square
City
Tehran
Province
Tehran
Postal code
1416663361
Phone
+98 21 8897 6527
Email
salma.ms219@gmail.com

2

Recruitment center
Name of recruitment center
Behesht traditional clinic
Full name of responsible person
Effat Jafari Dehcordi
Street address
847, Behest Street, Vahdat Islami Street,Hassan abad Square
City
Tehran
Province
Tehran
Postal code
1114733311
Phone
+98 21 5515 2191
Email
stm@iums.ac.ir

3

Recruitment center
Name of recruitment center
Skin and Stem Cell Research Center
Full name of responsible person
Parvin Mansouri
Street address
Tehran Province, Tehran, No 4 Maryam Dead End South Andarzgo Blvd, Kamraniyeh
City
Tehran
Province
Tehran
Postal code
19379511
Phone
+98 21 2220 1710
Email
tmarkaz@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazem Malakooti
Street address
Iran University of Medical Sciences, Besides Milad Tower, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
adminsite@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mahboobah Salmanian Haji Agha
Position
PhD Student of Traditional Medicine
Latest degree
Medical doctor
Other areas of specialty/work

Traditional Medicine

Street address
School of Traditional Medicine, Behest Street, Vahdat Islami Street, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 5563 9724

Email
salma.ms219@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mahboobah Salmanian Haji Agha

Position
PhD Student of Traditional Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
School of Traditional Medicine, Behest Street, Vahdat Islami Street, Tehran

City
Tehran

Province
Tehran

Postal code
1114733311

Phone
+98 21 5515 2192

Email
salma.ms219@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mahboobeh Salmanian haji agha

Position
PhD student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
School of Traditional Medicine, Behest Street, Vahdat Islami Street, Tehran

City
Tehran

Province
Tehran

Postal code
1114733311

Phone
+98 21 5563 9724

Fax

Email
salma.ms219@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
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
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