

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 communis* formulation versus clindamycin 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 *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)

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+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 patient, 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

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

Ahmadiieh traditionale clinic

Full name of responsible person

Lila Shirbeigi

Street address

North Sarparast Street, Palestine Square

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Tehran

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2

Recruitment center

Name of recruitment center

Behesht traditional clinic

Full name of responsible person

Effat Jafari Dehcordi

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847, Behest Street, Vahdat Islami Street,Hassan abad Square

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3

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center

Full name of responsible person

Parvin Mansouri

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Tehran Province, Tehran, No 4 Maryam Dead End South Andarzgo Blvd, Kamraniyeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

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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

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