Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the anti-acne effect of a cleanser containing myrtle essential oil entrapped in chitosan bead from Nik Ara Company on reducing acne, levels of moisture, pH, fat, elasticity, and skin melanin in patients with acne vulgaris

Protocol summary

Study aim
Investigating the anti-acne effect of a cleanser containing myrtle essential oil entrapped in chitosan bead from Nik Ara Company on reducing acne, levels of moisture, pH, fat, elasticity, and skin melanin in patients with acne vulgaris

Design
This study is a double-blind and parallel clinical trial that will be conducted in two groups of 30 people on patients with mild to moderate grade of acne vulgaris referred to the dermatologist.

Settings and conduct
Patients with mild to moderate acne vulgaris will be referred to two specialized treatment centers in Kerman and Gonabad.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: patients with mild to moderate acne vulgaris (based on the definition of comedone lesions, papules, and pustules), at least 12 years of age, willing to participate in the study, and complete the consent form. Exclusion criteria include: people with congenital or acquired immune deficiency, people with atopy and eczema and chronic skin diseases, people with severe acne that is accompanied by nodules and cysts that require systemic treatments, taking anti-acne treatments. In the past 4 weeks, such as peeling, laser, and antibiotic drugs, pregnant women, lactating women, and patients with polycystic ovary syndrome, people using drugs that cause acne, such as oral and topical steroids and anticonvulsant drugs.

Intervention groups
The intervention group received the wash containing the essential oil of the case entrapped in chitosan beads and the placebo group received the wash containing the essential oil of the case.

Main outcome variables
Acne grade, pH, fat level, darkness level, moisture and skin elasticity

General information

Reason for update

Acronym
CLEANIKA Anti-acne

IRCT registration information
IRCT registration number: **IRCT20240207060931N1**
Registration date: **2024-02-25, 1402/12/06**
Registration timing: **prospective**

Last update: **2024-02-25, 1402/12/06**
Update count: **0**

Registration date
2024-02-25, 1402/12/06

Registrant information

Name
Mohammad Hadi Nematollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3211 1890

Email address
nematollahi.mh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-03, 1403/01/15

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the anti-acne effect of a cleanser containing myrtle essential oil entrapped in chitosan bead from Nik Ara Company on reducing acne, levels of moisture, pH, fat, elasticity, and skin melanin in patients with acne vulgaris

Public title
The effect of Nik Ara Company's cleanser in the improvement of patients with acne vulgaris
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate acne vulgaris (based on the definition of comedone, papule, and pustule lesions). Minimum age of 12 people Willing to participate in the study and complete the consent form.
Exclusion criteria:
People with congenital or acquired immune deficiency People with atopy and eczema and chronic skin diseases People with severe acne that is accompanied by nodules and cysts that require systemic treatments Taking anti-acne treatments in the last 4 weeks such as peeling, laser, and antibiotic drugs Pregnant women, lactating women and polycystic ovary syndrome patients People using drugs that cause acne, such as oral and topical steroids and anticonvulsants
Age
From **10 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization process will be according to the stratified randomization method. Stratification of patients will be performed based on age, gender, and BMI, With the help of Winpepi software (V 11.6).
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient receives the drug or placebo in sealed envelopes that are coded. Coding is done by one of the colleagues of the project and the medicine, evaluator, and patient will be blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences, Medical UniversityCampus, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2024-02-12, 1402/11/23
Ethics committee reference number
IR.KMU.REC.1402.374

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
Changes in acne grade
Timepoint
Before the intervention and 56 days after the intervention
Method of measurement
Acne grade will be calculated based on the GAGS system (Global Acne Grading System) on days 0 and 8 weeks after using the drug and placebo.

2

Description
Changes in skin pH
Timepoint

Before the intervention and 56 days after the intervention

Method of measurement

Skin pH values will be measured by the MST1000 device.

3

Description

Changes in skin moisture

Timepoint

Before the intervention and 56 days after the intervention

Method of measurement

Skin moisture levels will be measured by the MST1000 device.

4

Description

Changes in skin fat level

Timepoint

Before the intervention and 56 days after the intervention

Method of measurement

Skin fat level values will be measured by the MST1000 device.

5

Description

Changes in skin elasticity

Timepoint

Before the intervention and 56 days after the intervention

Method of measurement

Skin elasticity values will be measured by the MST1000 device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergo clinical studies before starting the treatment, and the condition of their skin lesions is recorded using a high-contrast digital camera to accurately count and identify the type of lesions. Then, patients in the intervention group are prescribed a wash containing the essential oil trapped in chitosan beads. It should be noted that the intervention group will not be deprived of basic antibiotic treatment and washing agents will be prescribed as auxiliary treatment. Before starting the study and at the end of the 8th week after the start of treatment for all patients, the acne severity scoring system (GAGS)) the global acne grading system is performed. In this system, 6 areas are examined: the forehead, right cheek, left cheek, nose, chin, and the upper part of the trunk. And the nodule has 4 points. The presence of each of these signs on the chin and nose will be worth 1 point each, the forehead and each of the cheeks will be worth 2 points, and the chest and the back of the shoulders will be worth 3 points each. Finally, the overall grade of the severity of the disease was obtained from the product of the number and score of each lesion in their location and finally the sum of the resulting numbers. A score of 1 to 18 is mild acne, 19 to 30 is moderate acne, 31 to 38 is severe acne, and more than 39 is very severe acne.

Category

Treatment - Drugs

2

Description

Control group: Patients undergo clinical studies before starting the treatment, and the condition of their skin lesions is recorded using a high-contrast digital camera to accurately count and identify the type of lesions. Then, patients in the control group will be randomly prescribed an herbal cleanser containing essential oil without chitosan seeds. It should be noted that the control group will not be deprived of basic antibiotic treatment and washing agents will be prescribed as auxiliary treatment. Before starting the study and at the end of the 8th week after starting the treatment for all patients, scoring of acne severity based on the system (GAGS) The global acne grading system is done. In this system, 6 areas are examined: forehead, right cheek, left cheek, nose, chin and the upper part of the trunk. First, each lesion is scored according to its severity: according to this system, the presence of comedone 1, papule 2, pustule. 3, and the nodule has 4 points. The presence of each of these signs on the chin and nose will be worth 1 point each, the forehead and each of the cheeks will be worth 2 points, the chest and the back of the shoulders will be worth 3 points each. Finally, the overall grade of the severity of the disease was obtained from the product of the number and score of each lesion in their location and finally the sum of the resulting numbers. A score of 1 to 18 is mild acne, 19 to 30 is moderate acne, 31 to 38 is severe acne, and more than 39 is very severe acne.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian medicine clinic and Iranian supplements

Full name of responsible person

Dr. Mehrzad Mehrbani

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unit four, second floor, Pardis Complex, 15th alley, Shafa St.,

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2

Recruitment center
Name of recruitment center
Dr. Hamideh Mohammadzadeh's office
Full name of responsible person
Dr. Hamideh Mohammadpou
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the upper floor of Dr. Khakshor Pharmacy, the beginning of Nasser Khosro Street, Imam Khomeini Square, Gonabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mohammad Hadi Nematollahi
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Department of Clinical Biochemistry, Afzalipour Medical School, Kerman University of Medical Sciences, Haft Bagh Alavi Axis, Kerman University of Medical Sciences Campus, Kerman, Iran
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7616913555
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Grant name
Grant code / Reference number
402000166
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice-Chancellery for Research & Technology
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
Kerman University of Medical Sciences
Full name of responsible person
Mohammad Hadi Nematollahi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Hadi Nematollahi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Department of Clinical Biochemistry, Afzalipour Medical School, Kerman University of Medical Sciences, Haft Bagh Alavi Axis, Kerman University of Medical Sciences Campus, Kerman, Iran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

A part of the data such as the information related to the main outcome or the like can be shared.

When the data will become available and for how long

Access to study documentation after results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions, and also people who are working in the industry can apply for them.

Under which criteria data/document could be used

For secondary studies

From where data/document is obtainable

Applicants should submit their application to the relevant person introduced through email correspondence, after the applicant's application is reviewed by the members of the group, the documents will be sent to him. Address: Kerman University of Medical Sciences, Afzalipur Faculty of Medicine, Department of Biochemistry. Name of the respondent: Mohammad Hadi Nematollahi, phone and fax: 03433257448, e-mail address: mh.nematollahi@yahoo.com

What processes are involved for a request to access data/document

Applicants should submit their application to the relevant person introduced through email correspondence, after the applicant's application is reviewed by the members of the group, the documents will be sent to him. It should be noted that the responsible person for this project is in contact with the patients during the follow-up period. In addition, the data and documents related to this plan will be available to patients after completion and official release.

Comments