Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessing the Hydrating and Antimicrobial of Chitosan-based Facial Mack for the Treatment of Acne Vulgaris Patients

Protocol summary

Study aim

1-To evaluate the therapeutic effect of Chitosan-Facial Mask (CFM) facial mask in reducing skin acne. 2-To investigate the impact of CFM on skin fat reduction in patients with acne vulgaris. 3- To measure patient satisfaction in using CFM . 4- To assess the efficacy of NFM in reducing skin acne.

Design

The study will involve a sample of participants with moderate acne. Each participant will have their face divided into two halves: the left side and the right side. One side will be treated with a face mask, while the other side will follow a routine treatment. All participants (15 members). Treated half of face is persist during study. The study is parallel.

Settings and conduct

Patients with acne vulgaris referred to the dermatologist's office. After obtaining consent, they are enrolled in the study.

Participants/Inclusion and exclusion criteria

Acne vulgaris patients Inclusion Criteria; 1. Diagnosis of Acne Vulgaris. 2. Severity of Acne. Using standardized grading systems such as the Global Acne Grading System (GAGS) or the Investigator's Global Assessment (IGA). 3. No Internal Interventions. 4. Age Range: 12-65 5. Gender: - The study is open to both males and females. Exclusion criteria; 1. Patients with a history of other dermatological conditions (rosacea or dermatitis) or systemic diseases. 2.Pregnancy and Breastfeeding. 3.Medications: systemic corticosteroids or hormonal therapies. 4. Severe Acne.

Intervention groups

received CFM

Main outcome variables

Reducing the incidence of skin acne Reduce inflammation. Improved previous acne.

General information

Reason for update

The inconsistency between the title of the proposed study and the title of the proposal approved by the university's ethics committee poses a cause for concern.

Acronym

CFM

IRCT registration information

IRCT registration number: **IRCT20221113056487N1**
Registration date: **2023-11-26, 1402/09/05**
Registration timing: **prospective**

Last update: **2023-12-05, 1402/09/14**
Update count: **1**

Registration date

2023-11-26, 1402/09/05

Registrant information

Name

Mohammad Hossein Haddadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3334 6098

Email address

haddadi841@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-12, 1402/09/21

Expected recruitment end date

2024-02-10, 1402/11/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessing the Hydrating and Antimicrobial of Chitosan-based Facial Mack for the Treatment of Acne Vulgaris Patients

Public title
Assessing the Efficacy of Chitosan-Based Facial Masks in Acne Treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Moderate-Acne Vulgaris Patients
Exclusion criteria:
Pregnancy and Breastfeeding Autoimmune diseases and systemic diseases Rosacea or Dermatitis Severe acne vulgaris

Age
From **12 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
The participants will be instructed to apply the face mask to the designated half of their face according to the provided guidelines. Treated half of face is persist during study. The study will run for a period of six weeks, during which the participants will be monitored closely.

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study aims to examine the effectiveness of Chitosan 0.5% face masks in improving acne by conducting a half-face study design. In this design, one half of the face receives treatment with a face mask, while the other half undergoes routine treatment. By comparing the two areas, we can evaluate the specific impact of the face mask on acne improvement. The study will involve a sample of participants with moderate acne. Each participant will have their face divided into two halves: the left side and the right side. One side will be treated with a face mask, while the other side will follow a routine treatment. All participants divided into two groups with 15 members. The participants will be instructed to apply the face mask to the designated half of their face according to the provided guidelines. Treated half of face is persist during study. The study will run for a period of six weeks, during which the participants will be monitored closely. Regular evaluations will be conducted to assess the progress of acne improvement on both sides of the face. The evaluations will include visual examination, as well as the use of standardized acne severity scales to quantify the changes. The participants will also be asked to report any subjective improvements, such as reduced redness, inflammation, and overall skin texture.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Ilam University of Medical Sciences
Street address
Banganjab Ave. Pjohesh Blvd, Ilam university of medical science
City
Ilam
Province
Ilam
Postal code
6931678587

Approval date
2023-01-09, 1401/10/19

Ethics committee reference number
IR.MEDILAM.REC.1401.198

Health conditions studied

1

Description of health condition studied
Moderate-Acne Vulgaris

ICD-10 code
L70.0

ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
Reduce skin fat.

Timepoint
6 Weeks

Method of measurement
Abnormal shine of the skin, photography, presence of acne

2

Description
Average number of acne lesions
Timepoint
The average number of acnes is measured on the first day and then every two weeks.
Method of measurement
Observational.

3

Description
Average number of comedones
Timepoint
The average number of comedones is measured on the first day and then every two weeks.
Method of measurement
Observational.

4

Description
Average number of inflamed papules.
Timepoint
The average number of inflamed papules is measured on the first day and then every two weeks.
Method of measurement
Observational.

5

Description
The rate of recovery of lesions.
Timepoint
Every two weeks.
Method of measurement
Observational.

Secondary outcomes

1

Description
Satisfaction score of mask use.
Timepoint
The end of study.
Method of measurement
Questionnaire form of lay et al.

2

Description
Satisfaction score of skin fat mask.
Timepoint
The end of study.
Method of measurement
Questionnaire.

Intervention groups

1

Description
Intervention group: Recipient of the mask of magnetic nanoparticles conjugated to chitosan-betaine. The mask contains 97.5% Chitosan solution (0.5%) and 2.5% essential oil and menthol.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shadfar's dermatologist
Full name of responsible person
Fariba Shadfar
Street address
South Saadi St.
City
Ilam
Province
Ilam
Postal code
6931659687
Phone
+98 21 8670 5503
Email
faribashadfar03@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Abas Maleki
Street address
Banganjab ave., pajohesh Blvd, Ilam university of medical science
City
Ilam
Province
Ilam
Postal code
6931678588
Phone
+98 21 8670 5503
Email
haddadi841@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice-Chancellor for Research and Technology Affairs, Ilam University of Medical Science.

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
Ilam University of Medical Sciences
Full name of responsible person
Mohammd Hossein Haddadi
Position
Associate professor of medical biotechnology
Latest degree
Ph.D.
Other areas of specialty/work
Biotechnology
Street address
Banganjab Ave., Pajohesh Blvd., Ilam university of medical science
City
Ilam
Province
Ilam
Postal code
6931678588
Phone
+98 21 8670 5503
Email
haddadi841@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Mohammad Hossein Haddadi
Position
Associate professor of medical biotechnology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Banganjab Ave., Pajohesh Blvd., Ilam university of medical science
City
Ilam
Province
Ilam
Postal code
6931687588
Phone
+98 21 8670 5503
Email
haddadi841@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Mohammad Hossein Haddadi
Position
Associate professor of medical biotechnology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Banganjab Ave., Pajohesh Blvd., Ilam university of medical science
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Province
Ilam
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6931687588
Phone
+98 21 8670 5503
Email
haddadi841@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
Not applicable
Title and more details about the data/document
Photos taken in the first days and every two weeks.
When the data will become available and for how long
2026
To whom data/document is available
Vice-Chancellor for Research and Technology Affairs
Under which criteria data/document could be used
To clarify and use data to create artificial intelligence software
From where data/document is obtainable
Vice-Chancellor for Research and Technology Affairs
What processes are involved for a request to access data/document

Written request to the Vice President of Research and Technology, Ilam University of Medical Sciences

Comments