Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Study of the effects of Anaheal plus supplement on inflammation and scarring caused by acne

Protocol summary

Study aim
Examining the effects of Anaheal Plus supplement on the healing of acne scars, Examining the change in the surface of acne spots with Anaheal Plus, Examining the change in inflammation caused by acne with Anaheal Plus, Examining the change in the number of lesions caused by acne scars with Anaheal Plus

Design
Clinical trial with control group, based on community and practical, on 50 patients

Settings and conduct
The method of conducting this study will be a clinical trial and the participating patients will be selected from the patients of the clinics and hospitals of Tehran Islamic Azad University. After receiving Anaheal Plus supplement by the first group and receiving placebo by the second group, both groups will be examined at the end of the study in terms of changes in the level and intensity of the spots caused by acne, as well as the number of acne lesions and the degree of inflammation and redness of the lesions. The informed consent form prepared in advance will also be provided to the patients so that they are fully familiar with the study process.

Participants/Inclusion and exclusion criteria
Patients over 18 years old with acne scars

Intervention groups
50 patients above 18 years with acne scars who have been confirmed by a dermatologist will be selected and half of these people, who will be placed in the intervention group by using a random number table, will receive A H A exfoliator and Anaheal Plus supplement for one month. Considered variables will be checked one month after the start of the treatment. The rest of the studied patients will be in the control group and will receive A H A exfoliator like the intervention group, with the difference that they will receive placebo instead of Anaheal plus.

Main outcome variables
Number of lesions, Area of the scar, Inflammation, Redness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150706023084N17**
Registration date: **2023-08-22, 1402/05/31**
Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**
Update count: **1**

Registration date
2023-08-22, 1402/05/31

Registrant information

Name
MARYAM SHIEHMORTEZA

Name of organization / entity
AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country
Iran (Islamic Republic of)

Phone
+98 212640056

Email address
shiehmorteza@iaups.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effects of Anaheal plus supplement on inflammation and scarring caused by acne

Public title
Anaheal plus effect on acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Acne scarring Age range over 18 years

Exclusion criteria:
Allergy to pineapple, curcuma, celery, carrot and fennel Pregnancy Lactation Renal failure (GFR<30) liver failure (Child pugh B,C) Hemophillia Using two antiplatelet drug Using one anti platelet and one anti coagulant drug

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize the study, each patient is assigned a code (1 or 2) using Rand number. Conventionally, the patient who received code one will receive drug and the patient who received code two will receive placebo. It should be noted that the patients will not know what code they have received and only the researcher will be aware of this issue.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be Single blinded in such a way that the participants will not be aware of the contents of the medicine package they receive. A code will be assigned to each patient using a Rand number. Patients whose code is 1 will receive the drug, and patients who are assigned a code of 2 will receive a placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Department of Pharmaceutical Sciences,Tehran Islamic Azad University of Medical

Street address
Dr Shariati Ave., Gholhak, Yakhchal Ave., Islamic Azad University of Pharmaceutical Sciences Branch

City
Tehran

Province
Tehran

Postal code
۱۹۳۹۵۶۴۶۶

Approval date
2023-05-24, 1402/03/03

Ethics committee reference number
IR.IAU.PS.REC.1402.100

Health conditions studied

1

Description of health condition studied
Acne

ICD-10 code
L70

ICD-10 code description
Acne

Primary outcomes

1

Description
The number of lesions caused by acne scars

Timepoint
30 days

Method of measurement
Observational

2

Description
Area of scar caused by acne

Timepoint
30 days

Method of measurement
Measure with a ruler

3

Description
Inflammation

Timepoint
30 days

Method of measurement
According to dermatologist opinion

4

Description

Redness

Timepoint

30 days

Method of measurement

According to dermatologist opinion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 25 patients above 18 years with acne scars who have been confirmed by a dermatologist will be selected and receive A H A exfoliator once a day on the areas which have acne scars and also they will consume Anaheal Plus supplement which contains bromelain and curcumin and is produced by Salamat parmoon amin pharmaceutical Co. two times a day (One in the morning and one in the evening) for one month. Considered variables will be checked one month after the start of the treatment.

Category

Treatment - Drugs

2

Description

Control group:25 patients will be in the control group and will receive A H A exfoliator like the intervention group, with the difference that they will receive placebo capsule which is produced by Salamat parmoon amin pharmaceutical Co. twice a day for one month instead of Anaheal plus.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu ali hospitol

Full name of responsible person

Saba Shojaan

Street address

Damavand Street - not reaching Imam Hossein Square - Bu Ali Hospital

City

Tehran

Province

Tehran

Postal code

1711734365

Phone

+98 21 3334 8036

Email

booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Salamat Parmoon Amin Pharmaceutical company

Full name of responsible person

Mohammad Reza Anbiaei

Street address

West Nafisi, Baradaran Sarafha Ave, Saadat abad Ave.

City

Tehran

Province

Tehran

Postal code

1998863174

Phone

+98 21 8869 1099

Email

info@spameda.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Salamat Parmoon Amin Pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Shiehmorteza

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

No. 99, Yakhchal street, Dr Shariati Ave.

City

Tehran

Province

Tehran

Postal code

1916893813

Phone
+98 21 2264 0056
Email
Shiehmorteza@iaups.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Shiehmorteza
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
No 99, Yakhchal Ave, Dr Shariati
City
Tehran
Province
Tehran
Postal code
۱۹۱۶۸۹۳۸۱۳
Phone
+98 21 2264 0056
Email
Shiehmorteza@iaups.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Saba Shojaan
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
No. 99, Yakhchal Ave, Dr Shariati
City
تهران
Province
Tehran
Postal code
1918943935
Phone
+98 21 2264 0056
Email
sabashojaan@yahoo.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
Data are collected in the form of a questionnaire
When the data will become available and for how long
After the intervention
To whom data/document is available
Qualified persons
Under which criteria data/document could be used
Used for scientific advancement in the field under study
From where data/document is obtainable
Clinical office of Islamic Azad University,Medical science of Tehran, Faculty of pharmacy
What processes are involved for a request to access data/document
Request in writing by going through legal procedures
Comments