Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Assessment of the therapeutic effects of Anaheal plus supplement in patients with contact dermatitis

Protocol summary

Study aim
Investigating the therapeutic effect of Anahil Plus supplement in patients with contact dermatitis

Design
clinical trial with control groups, community-based and pragmatic, with a parallel group, single-blind, randomized, on 50 patients

Settings and conduct
This study was performed on patients over 12 years old with contact dermatitis who reffered to the Tehran Islamic Azad University Hospitals , and the first group will receive Anahil Plus, which contains bromelain and curcumin, and the second group will receive a placebo that contains lactose . The number of patients is 50, which was announced by a statistician based on the number of patients with contact dermatitis who visited the office in the last year and in a period of three months. Each of the experimental and control groups includes 25 people. Patients will participate in the study according to the doctor's diagnosis of having contact dermatitis and according to demographic information and personal consent and will be placed in one of the control or experimental groups. The informed consent form that has been prepared in advance will be provided to the patients so that they are fully familiar with the study process.

Participants/Inclusion and exclusion criteria
Adult patients (over 12 years old) with contact dermatitis; Allergy to pineapple, celery, carrot and fennel, having hemophilia, taking two anti-platelet drugs or one anti-platelet drug and an anticoagulant, severe kidney failure (GFR<30), severe liver failure (Child pugh B, C), Pregnant, lactating women

Intervention groups
Adult patients with contact dermatitis who will receive Anahil Plus supplement in addition to standard treatment (moisturizer).In control group in addition to the standard treatment, they will receive a placebo that contains lactose.

Main outcome variables
The surface of the affected area, redness, inflammation, itching

General information

Reason for update
The code of ethics and sponsor was entered incorrectly

Acronym

IRCT registration information
IRCT registration number: **IRCT20150706023084N16**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2023-11-06, 1402/08/15**
Update count: **1**

Registration date
2023-08-21, 1402/05/30

Registrant information

Name
MARYAM SHIEHMORTEZA

Name of organization / entity
AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country
Iran (Islamic Republic of)

Phone
+98 212640056

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shiehmorteza@iaups.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the therapeutic effects of Anaheal plus supplement in patients with contact dermatitis

Public title

Anaheal plus supplement in contact dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (over 12 years old) Patient with contact dermatitis

Exclusion criteria:

Allergy to pineapple, celery, carrot and fennel having hemophilia taking two anti-platelet drugs or one anti-platelet drug and an anticoagulant severe kidney failure (GFR<30) severe liver failure (Child pugh B, C) Pregnancy lactation

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

After the diagnosis of the disease by the dermatologist, using the rand number site, each patient was assigned a number.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is conducted in single blind way, so that the patients are not aware of the contents of the received packages that contain Bremelin and Curcumin or placebo. Conventionally, the packages containing supplement number one and the packages containing placebo number two. We attribute Using rand number, we determine whether to give medicine or placebo to each patient.

Placebo

Used

Assignment

Parallel

Other design features

For all patients (both test group and control group), we prescribe the standard treatment that is moisturizing. In addition to the standard treatment, the test group also receives Anahil Plus supplement twice a day. The control group will receive a placebo instead of a supplement. After a month, we will re-examine the factors of the involvement level, redness, inflammation and itching.

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

193956466

Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.IAU.PS.REC.1402.101

Health conditions studied

1

Description of health condition studied

Irritant contact dermatitis

ICD-10 code

L24.9

ICD-10 code description

Irritant contact dermatitis, unspecified cause

Primary outcomes

1

Description

The surface of the affected area

Timepoint

30 days

Method of measurement

Measuring with a ruler

2

Description

Redness

Timepoint

30 days

Method of measurement

According to REEDA

3

Description
Edema
Timepoint
30 days
Method of measurement
According to REEDA

4

Description
itching
Timepoint
30 days
Method of measurement
Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: including 25 patients who are diagnosed with contact dermatitis by a dermatologist and consume Anahil Plus supplement produced by the company (two tablets daily) plus moisturizer as a standard treatment for 30 days. The questionnaire form is filled at the beginning and after one month.
Category
Treatment - Drugs

2

Description
Control group:includes 25 patients who are diagnosed with contact dermatitis by a dermatologist and use standard moisturizer as a treatment for 30 days along with a placebo containing lactose. The relevant questionnaire is filled at the beginning and 30 days later.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Booali hospital
Full name of responsible person
Hanieh Jalalian Targhi
Street address
Damavand Street, not reaching Imam Hossein Square, Bu Ali Hospital
City
Tehran
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Tehran
Postal code
1711734365
Phone
+98 21 3334 8036
Email
Booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Parmoon Salamat Amin Pharmaceutical Company
Full name of responsible person
Mohammad Reza Anbiaei
Street address
West Nafisi Alley, Baradaran Sarafha St, 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?
Yes
Title of funding source
Parmoon Salamat 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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
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Maryam Shiehmorteza
Position
Associated professor
Latest degree
Specialist
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Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hanieh Jalalian Targhi
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
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Email
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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 foe 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