# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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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**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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**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**
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**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
**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Hanieh Jalalian Targhi
**Position**
Pharmacy student
**Latest degree**
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**Other areas of specialty/work**
Medical Pharmacy
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**Phone**
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**Email**
Hjalaliant@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**
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**