

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Safety and efficacy of Linola F® Cream (Dr. August Wolf Co) on mild to moderate forms of atopic dermatitis

Protocol summary

2016-08-04, 1395/05/14

Summary

Atopic dermatitis, a chronic inflammatory disease, and itching of the skin. Studies have shown that patients with atopic dermatitis are deficient in Gamma Linolenic Acid (GLA) and Essential Fatty Acids (EFA) groups. Linola F manufactured by Dr. August Wolff is a cream containing 60% fat (structural fat rich in Linolenic acid). This study is a Phase III clinical trial with one group of patients in Split Body Trial design with mild to moderate atopic dermatitis severity (SCORAD below than 12) referred to the Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences, Tehran, Iran. When patients came to the clinic of the center, first they are evaluated by experts based on the inclusion and exclusion criteria (Visit 0), then for each patient two symmetrical lesions with the same intensity are selected and each lesion will be treated based on per-mutated block randomization of size 2, one lesion with Linola F® cream and the opposite side with routine moisturizing cream which patients commonly have used. sample size is 25 patients, also evaluator and allocator of treatment are different persons. The aim of this study is to evaluate the efficacy of the Linola F® and its impact on the physiology of the patients skin with atopic dermatitis, in comparison with routine moisturizing products in an Iranian population.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062017994N1**

Registration date: **2016-08-04, 1395/05/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Mansour Shamsipour

Name of organization / entity

Clinical Trial Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6690 1205

Email address

shamsipour@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Sina Tejarat Pishgam® Company

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of Linola F® Cream (Dr. August Wolf Co) on mild to moderate forms of atopic dermatitis

Public title

Linola F® on Skin Physiology of patients with atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Case of Mild to moderate atopic

dermatitis Aged (>2) years old At least 2 lesions on arms or legs with identical local SCORAD Written Informed Consent Having a negative pregnancy test Willingness to actively participate in the study and to come to the scheduled visits respectively willingness of parents/legal guardians to actively participate in the study and to come to the scheduled visits Willingness to discontinue the use of any conventional skin care products (e.g. creams, lotions, sunscreens) at the treatment areas of Linola F throughout the course of the study Exclusion Criteria: Pregnancy or lactation Severe Atopic eczema (local SCORAD >12) Drug addicts, alcoholics One of the following serious illnesses, if not medicated: cardiovascular diseases, asthma, hypertension Active skin disease at test area (except atopic dermatitis) Moles, tattoos, scars, hairs, dark pigmentation etc. at the test area that could influence the investigation Documented allergies to cosmetic products History of HIV History of Hepatitis C History of Hepatitis B Being involved in any other research project /clinical trial

Age

From **2 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University Of Medical Sciences(TUMS)

Street address

Tehran, Enghelab Ave., St. pour Sinai, Deputy of Science and Technology of Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2015-06-14, 1394/03/24

Ethics committee reference number

IR.TUMS.REC.1394.32

Health conditions studied**1****Description of health condition studied**

Atopic dermatitis with mild to moderate severity (SCORAD below than 12))

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes**1****Description**

Trans Epidermal Water Loss(TEWL)

Timepoint

Visit 0, 2 week after Visit 0, 4 week after Visit 0

Method of measurement

MPA

2**Description**

Corneometer

Timepoint

Visit 0, 2 week after Visit 0, 4 week after Visit 0

Method of measurement

MPA

Secondary outcomes**1****Description**

SCORAD Measure

Timepoint

Visit 0, 2 week after Visit 0, 4 week after Visit 0

Method of measurement

SCORAD

2**Description**

Burning, Itching, Temperature, Sebum, PH ,Mexameter

Timepoint

v

Method of measurement

MPA, calculating measures

3**Description**

Thickness , Density

Timepoint

Visit 0, 2 week after Visit 0, 4 week after Visit 0

Method of measurement

Ultrasonography

4

Description

Satisfaction with the solution treatment

Timepoint

2 week after Visit 0, 4 week after Visit 0

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention: Linola F® cream, twice a day at the site of disease (Only one side of the body, one hand or one foot)

Category

Treatment - Drugs

2

Description

Control: moisturizing routine in the opposite lesion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr. Alireza Firoz

Street address

No. 415, Taleqni Ave., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sina Tejart Pishgam® company

Full name of responsible person

Mahdi Moazami Godarzi

Street address

Molsadra Ave., Shiraz Street North, St. western Zayandehrod, No. 12 F, Unit 11

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sina Tejart Pishgam® company

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Centre for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr Alireza Firooz

Position

Dermatologist, Professor

Other areas of specialty/work

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Full name of responsible person

Dr Alireza Firooz

Position

Dermatologist, Professor

Other areas of specialty/work

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty