

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of the efficacy of cryotherapy and 0.1 % acnalen gel vs. cryotherapy alone in the treatment of actinic keratoses: a randomized, double-blind clinical trial

Protocol summary

Summary

The purpose of this study is to evaluate the efficacy of cryotherapy followed by Acnalone 0.1% gel. This study is a randomized, double-blind clinical trial. Cryotherapy is performed for 100 patients with single freeze-thaw cycle which forms a 2mm ring around the lesions, then patients receive either Acnalone gel and placebo from 10th day to 3 months (90 days). Drugs are applied twice daily on entire affected area of skin. Patients are evaluated on days 10, 40, 70, and 100 of the study. The outcome measure is estimated by reducing the number of lesions in the treated areas.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010104901N1**

Registration date: **2010-10-31, 1389/08/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-31, 1389/08/09

Registrant information

Name

Hmideh Azimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Aburaihan company

Expected recruitment start date

2010-01-05, 1388/10/15

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of cryotherapy and 0.1 % acnalen gel vs. cryotherapy alone in the treatment of actinic keratoses: a randomized, double-blind clinical trial

Public title

Comparison of the efficacy of cryotherapy and 0.1 % acnalen gel vs. cryotherapy alone in the treatment of actinic keratoses: a randomized, double-blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Clinical diagnosis of actinic keratosis, At least 5 lesions, Willing to participate in the study
Exclusion criteria: Pregnancy (first trimester), Previous history of allergy to drugs of study, Use of destructive methods or drugs for treatment of lesions over the last month, Use of Isotretinoine over the last 2 months, Use of peeling methods over the last month, Participation in the other clinical studies over the past month

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz University Of Medical Sciences

Street address

Golgasht Ave

City

Tabriz

Postal code**Approval date**

2010-06-24, 1389/04/03

Ethics committee reference number

54/1745

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

Actinic keratoses

ICD-10 code**ICD-10 code description**

Actinic keratoses

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

Clearance of lesions

Timepoint

Baseline and then monthly

Method of measurement

Number of lesions

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

Side effects

Timepoint

Monthly

Method of measurement

Medical history and physical examination

Intervention groups**1****Description**

Cryotherapy at the beginning + Acnalene 0.1% gel twice daily for 3 months

Category

Treatment - Drugs

2**Description**

Control group: Cryotherapy at the begining + placebo twice daily for 3 months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina hospital

Full name of responsible person**Street address**

Azadi Ave

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Aburaihan Company

Full name of responsible person

Dr M.Hakimi

Street address

No 1, Tirandaz Ave, Tehranpars threeway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Aburaihan 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

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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