Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Acnalene 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 Acnalene 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)

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+98 41 1331 1819

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azimihamideh@tbzmed.ac.ir

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 size
Target 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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahnaz Jaberian

Position

Resident of dermatology

Other areas of specialty/work

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Position

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jaberian_m@hotmail.com

Web page address

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