Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical trial of comparing the effect of ammonium lactate 14% and IPL versus ammonium lactate 14%-alone on keratosis pilaris

Protocol summary

Summary

1) Objective: The aim of this study is comparison of efficacy between Ammonium lactate 14% and IPL and Ammonium lactate 14% alone on keratosis pilaris. 2) Design: This study is a randomized clinical trial. 3) Setting and conduct: The patients with keratosis pilaris in dermatology clinic will be randomly divided into two groups (25 in each one). 4) Intervention: After taking consent, one group receives topical Ammonium lactate 14% for 3 months and the other group receives IPL in addition to topical treatment, 3 times with a month interval starting from the end of first month. 5) Main outcome measures: improvement assessed by two independent dermatologists blinded to the randomization process and by means of serial photography. 6) Participants: Inclusion criteria: patients who don't tend to only longterm and topical treatment and they prefer laser treatment; no pregnancy and breastfeeding and consent to participate in the study. Exclusion criteria include irregular returns and sensitivity to Ammonium lactate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428448N1**
Registration date: **2016-12-07, 1395/09/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

Name

Siamak Rahmani

Name of organization / entity

Isfahan University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

siamakrahmani@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparing the effect of ammonium lactate 14% and IPL versus ammonium lactate 14%-alone on keratosis pilaris

Public title

The effect of ammonium lactate 14% and IPL on keratosis pilaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:being afflicted with keratosis pilaris; patients who don't tend to only longterm and topical treatment and they prefer laser treatmen; no pregnancy and breast feeding and consent to participate in the study. Exclusion criteria:sensitivity to Ammonium lactate;

no regular visits and using cotreatments.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Using a table of random number, random sampling was conducted.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezarjarib street, Isfahan, Iran

City
Isfahan

Postal code

Approval date
2016-01-13, 1394/10/23

Ethics committee reference number
IR.MUI.REC.1394.3.760

Health conditions studied

1

Description of health condition studied
Keratosis pilaris

ICD-10 code
L85.8

ICD-10 code description
Other specified epidermal thickening

Primary outcomes

1

Description
Clinical improvment

Timepoint
Before, 1 month after final treatment and 2 month after final treatment

Method of measurement
Photography evaluation by two blinded dermatologist

Secondary outcomes

1

Description
Improvements Vas score

Timepoint
Before, 1 month after final treatment and 2 month after final treatment

Method of measurement
Question from patient

Intervention groups

1

Description
Control group receives topical ammonium lactate 14% making the company noreva twice a day used as a thin layer on the waste for 3 months.

Category
Treatment - Other

2

Description
In treatment group we done 3 IPL sessions with 4 weeks interval and also advised the patients to apply topical ammunium lactate 14% making the company noreva twice a day used as a thin layer on the waste for 3 months. the setting of IPL was: 530-1100nm wavelength, one pass, fluence of 14-16 J/cm2, and program of 14-18.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Siamak Rahmani

Street address
Dermatology Department, Alzahra hospital, Sofe street, Isfahan, Iran

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor foer research of Isfahan University of Medical Sciences

Full name of responsible person
Mehdi Nematbakhsh

Street address
Vice Chancellor for Research, Isfahan University Of Medical Science, Hezarjarib Street, Isfahan, Iran

City
Isfahan

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Vice Chancellor foer research of Isfahan University of Medical Sciences

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
Isfahan University of Medical Science

Full name of responsible person
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Position
Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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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