

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 31 3627 2548

##### 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 treatment; 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 improvement

**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 ammonium 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/cm<sup>2</sup>, 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**

Siamak Rahmani

**Position**

Resident

**Other areas of specialty/work****Street address**

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## Person responsible for scientific

## inquiries

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**Full name of responsible person**

Amirhossein Siadat

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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*