

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

A comparative study of efficacy and safety of Glycolic acid 70% peel with topical Tretinoin 0.05% in the treatment of Acanthosis Nigricans patients

Protocol summary

Study aim

Comparison of efficacy and safety of Glycolic acid 70% peel with topical Tretinoin 0.05% in the treatment of Acanthosis Nigricans patients.

Design

30 Acanthosis Nigricans patients with involvement of axilla or neck enter this study. During baseline appointment, demographic features and BMI for each patient is documented and baseline photographs are obtained. Randomly each patient is treated with Glycolic acid 70% chemical peel every 2 weeks for 4 sessions for lesions on one side of the body and with topical Tretinoin 0.05% every other night on the opposite side. On week 8 new photographs are obtained and compared with baseline photographs, then the patient, the project manager and 2 other dermatologists rank the response rate to each treatment.

Settings and conduct

Chemical peeling with Glycolic acid 70% will be performed by the project manager on the lesions of one side every 2 weeks at Razi hospital. Tretinoin cream will be provided by the project manager for the patients during the baseline appointment and instructions will be provided. The patients and the project manager rank the response rate and side effect of treatments unblinded at 8th week, but 2 other dermatologist will be blinded.

Participants/Inclusion and exclusion criteria

Acanthosis Nigricans patients with 1) Axilla or neck involvement 2) 12 years of age or older 3) Signing the Informed consent 4) no previous treatment of the lesions in the past month 5) willingness for participation in the study Items leading to exception from the study 1) Contraindication for topical Tretinoin and/or Glycolic acid 2) Pregnancy and lactation 3) underlying malignancy

Intervention groups

Each patient is treated with Glycolic acid 70% chemical peel every 2 weeks for 4 sessions on one side of the lesions and with topical Tretinoin 0.05% every other night on the opposite side.

Main outcome variables

Clinical improvement of the lesions/ Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221129056666N1**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **retrospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Rana Samii

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2280 7479

Email address

raanasamiei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of efficacy and safety of Glycolic acid 70% peel with topical Tretinoin 0.05% in the treatment of Acanthosis Nigricans patients

Public title

Acanthosis Nigricans project

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Acanthosis Nigricans lesions of axilla or neck. Patients with the informed consent for participating in the study.

Exclusion criteria:

Pregnancy or Lactation Patients with underlying malignancy. Patients with contraindications for topical Tretinoin or Glycolic acid. History of treatment of the lesions in the past month.

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each patient is treated with topical Tretinoin on one side of neck or axilla, and with Glycolic acid on the other side.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was used in this study. In this method simple randomization models like tossing a coin, using randomized number tables or computerized methods of randomization is used. In this method each case is allocated in one group (Tretinoin or Glycolic acid) by tossing a coin for example. Some advantages of this method are unpredictability of treatment used for each side. Implementing of this method is simple. Randomization unit of this study is each case. Randomization software was used for randomization. This software gave us the ability to choose a desired method of randomization among several others. Randomization sequence was created using randomizer software. The sequence was created asking the software to divide 60 cases in to two groups of 30 (0 or 1) equally. Central allocation concealment was used in this study. In this method randomization sequence is available for the manager of the study to apply to the patients accordingly.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Since Acanthosis Nigricans lesions develop symmetrically in patients, each patient is treated with topical Tretinoin on one side and with Glycolic acid on the other side, in order to compare the efficacy of these two treatments in each patient with the identical parameters. Since each side of the patient is treated with a different form of treatment, it is impossible to blind the patients. The specialists that evaluate the outcome of these treatments are however blinded.

Secondary Ids

empty

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

Ethics committee of Tehran University of Medical Sciences school of Medicine

Street address

Room no. 604 , 6th floor, Tehran University of Medical Sciences main campus, Qods St. , Keshavarz Blvd. , Tehran

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-12-19, 1400/09/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1062

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

Acanthosis Nigricans

ICD-10 code

L83

ICD-10 code description

Acanthosis nigricans

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

Degree of resolution of Acanthosis Nigricans lesions

Timepoint

8 weeks after initiation of therapy and 4 treatment sessions

Method of measurement

Comparison with pre treatment photographs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acanthosis Nigricans lesions of one side of the axilla/ groin is treated with Glycolic acid 70% for 4 sessions every 2 weeks. The result of treatment is compared with initial photographs 2 weeks after the last session.

Category

Treatment - Drugs

2

Description

Intervention group: The opposite side of axilla/ groin will be treated with topical Tretinoin cream 0.05% every other night. The result of this treatment is compared with initial photographs after 8 weeks of treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Rana Samii

Street address

Vahdat Eslami Sq.

City

Tehran

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Postal code

1199663911

Phone

+98 21 5563 0223

Email

razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of medical sciences, Keshavarz

Blvd.

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Phone

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Rana Samii

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Rana Samii

Position

Resident

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All non recognizable patients information, study design, analytic studies, and the informed consent will be available for publication.

When the data will become available and for how long

6 months after submission

To whom data/document is available

All the scientist, professors who are studying in the field of dermatology, endocrinology, and pharmacology.

Under which criteria data/document could be used

For future studies.

From where data/document is obtainable

Via email to the submitted email address.

What processes are involved for a request to access data/document

After submission of their request along with their CV and the propose of their request to may email.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Rana Samii

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

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