

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the treatment effect of microneedling with topical retinoid in patients with comedonal acne

Protocol summary

Study aim

Comparison of the treatment effect of microneedling with topical retinoid in patients with comedonal acne

Design

In this research 82 patients with comedonal acne referring to rasoul akram hospital were chosen. Then they were randomly divided into two control and intervention groups.

Settings and conduct

Patients with comedonal acne referring to rasoul akram hospital are divided into case and control groups. In the case group, microneedling is done every two weeks and for a total 6 sessions. In the control group, medical treatment is done with every other night use of topical retinoid. Treatment course is 3 months for both groups. Patients under treatment with microneedling in every session and patients under treatment with topical retinoid are evaluated every month. They are also followed 3 months after the end of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with comedonal acne with any age and sex
Exclusion criteria: patients having inflammatory and severe acne/Patients under treatment with systemic drugs against acne

Intervention groups

Patients with comedonal acne referring to rasoul akram hospital are divided into case and control groups. In the case group, microneedling is done every two weeks and for a total 6 sessions. In the control group, medical treatment is done with every other night use of topical retinoid. Treatment course is 3 months for both groups. Patients under treatment with microneedling in every session and patients under treatment with topical retinoid are evaluated every month. They are also followed 3 months after the end of treatment.

Main outcome variables

Comparing the treatment effect of microneedling with topical retinoid in patients with comedonal acne

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140624018210N7**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Elham Behrangi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 2040

Email address

behrangi.e@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

iran university of medical sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the treatment effect of microneedling with topical retinoid in patients with comedonal acne

Public title

Comparing the treatment effect of microneedling with topical retinoid in patients with comedonal acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients having comedonal acne with any age and sex

Exclusion criteria:

Patients having inflammatory and severe acne/Patients under treatment with systemic drugs against acne

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 82

Randomization (investigator's opinion)

Randomized

Randomization description

Simple block randomization with statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcomes are evaluated by the attending of trial and data analysis is done by a methodologist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of iran university of medical sciences

Street address

East Shahid Hemmat expay, Iran university of medical sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2016-10-14, 1395/07/23

Ethics committee reference number

IR.IUMS.REC 1395.9411166001

Health conditions studied

1

Description of health condition studied

acne

ICD-10 code

L70.0

ICD-10 code description

acne vulgaris

Primary outcomes

1

Description

acne severity

Timepoint

Cases: every two weeks during treatment and 3 month after treatment cessation/Controls: every month during treatment and 3 months after treatment cessation

Method of measurement

Subjective assesment by the patient and with a questionnaire/objective assesment by the physician and based on acne severity index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group microneedling in done every 2 weeks and for a total 6 seessions. Control group: In this group topical retinoid in used every other night and for a total 3 months.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Saba Sepasgozar

Street address

Rasoul Akram hospital, Niayesh street, Sattarkhan street, Tehran

City

Tehran

Province
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Postal code
1313114456
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+98 21 6435 2378
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sabasepasgozar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mehrdad Eftekhari
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Iran university of medical sciences,East Shahid
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Email
mehrdad.eftekhari@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Saba Sepasgozar
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work

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Fax

Email

sabasepasgozar@gmail.com

Web page address

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

research datas

When the data will become available and for how long

Availability 6 months after the end of clinical trial

To whom data/document is available

Dermatologists

Under which criteria data/document could be used

In the case of comparision with other similar trials

From where data/document is obtainable

Iran university of medical sciences

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

Central library of Iran university of medical sciences

Comments