Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
Comparision of the treatment effect of microneedling with topical retinoid in patients with comedonal acne

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

Settings and conduct
Patients with comedonal acne reffering 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 inflamatory and severe acne/Patients under treatment with systemic drugs against acne

Intervention groups
Patients with comedonal acne reffering 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)

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+98 21 6650 2040

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behrangi.e@iums.ac.ir

Recruitment status
Recruitment complete

Funding source
iran university of medical siences

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 inflamatory 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 siences
Street address
East Shahid Hemmat expay,Iran university of medical siences
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 seesions.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
Phone
+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 Eftekhar
Street address
Iran university of medical siences,East Shahid Hemmat expway,Tehran
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mehrdad.eftekhar@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
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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
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 siences
What processes are involved for a request to access data/document
Central library of Iran university of medical siences
Comments