Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of Effectiveness, Morbidity, Tolerability and Satisfaction of Vitiligo Treatment with Microneedling with N-acetylcysteine Mesotherapy Compared with Microneedling alone: a Randomized Clinical Trial

Protocol summary

Study aim
Evaluation of Effectiveness, side effects, tolerability and satisfaction of microneedling therapy with N acetylcysteine in the treatment of stable vitiligo

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 20 patients. A simple randomization method is used.

Settings and conduct
Patients are selected from the dermatology clinic of Rasoul Akram Hospital and treatment and follow-up sessions are held in weeks 0, 2, 4, 6, 8, 10, 14. duration of each session is 15 minutes. In this study, participants and the evaluator were blinded so that patients were not informed about the drug used and the evaluator was not aware of the treatment process.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with symmetrical stable vitiligo who are between 15-75 years old and have not progressive lesions or new lesions in at least the past year and have not been treated in the past two months. Exclusion criteria: Patients who have thyroid disorders or allergy to N-acetylcysteine, are pregnant or breastfeeding, or intend to become pregnant within the next six months, patients who have a history of hypertrophic and colloidal scars, or pathological lesions , sores and infections at the site of microneedling .

Intervention groups
Intervention group: we use 1-2 cc of Exir Company 5% N-acetylcysteine ampule on the lesion and microneedle it until occurring the pinpoint bleeding. 4.7% N-acetylcysteine cream (4.7 g N-acetylcysteine powder in 95.3 g Eucerin) is also use once a day for 2.5 months and treatment sessions continue for 6 sessions every two weeks. Control group: we use distilled water on the lesion as a placebo and microneedle it until occurring the pinpoint bleeding. the treatment continue for 6 sessions every two weeks

Main outcome variables
Tensity of lesions, Intensity of repigmentation, Treatment Tolerance, Treatment satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200826048531N1**
Registration date: **2022-02-10, 1400/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-10, 1400/11/21**
Update count: **0**

Registration date
2022-02-10, 1400/11/21

Registrant information

Name
Elham Ziaeifar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2207 5125

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness, Morbidity, Tolerability and Satisfaction of Vitiligo Treatment with Microneedling with N-acetylcysteine Mesotherapy Compared with Microneedling alone: a Randomized Clinical Trial

Public title

Evaluation of the effect of microneedling and N-acetylcysteine in the treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with vitiligo have symmetrical constants patches They are between 15-75 years old No progressive or new lesions for at least the past year They have not been treated in the last two months

Exclusion criteria:

Patients who have thyroid disorders Patients with hypertrophic and keloid scars. At the site of microneedling have pathological lesions, wounds and infections. Patients who have allergies to N-acetylcysteine . Patients who are pregnant or breastfeeding. Patients who plan to become pregnant within the next six months.

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

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

Any vitiligo patch that is symmetrical on either side of the trunk, limb, or face of the patient.

Randomization (investigator's opinion)

Randomized

Randomization description

This study is performed on 20 patients and in each patient, two lesions are selected by the therapist that are approximately appropriate in terms of location and size, and one lesion is on the right side and the other on the left side of the body or face or limbs. Simple randomization method is used in such a way that for right sided lesion by selecting the letters A, B randomly from inside the envelope, the treatment method is determined and the other method will be used for the left sided lesions. The letter A indicates the main treatment method and the letter B symbolizes the placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is blind for the participant and the evaluator. At the beginning of the study, the procedure of treatment and receiving the drug, randomly receiving of a main drug for one lesion and a placebo for another one, is explained for all the participants, including both the intervention group and the control group. During the treatment process, the patients, without knowing if they are receiving the main drug (N-acetylcysteine ampoule) or placebo (visually similar to the main drug), are treated. After ending the treatment, the data is provided to a dermatologist as the evaluator. This person evaluates the outcome of the study without knowing the treatment process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of faculty of medicine at Iran University of Medical Sciences

Street address

Fifth Floor ,Office Center ,Iran University of Medical Sciences، next to Milad tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-08-08, 1399/05/18

Ethics committee reference number

IR.IUMS.FMD.REC.1399.309

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description
Tensity of lesions
Timepoint
At the beginning of the study (before the intervention) and 2, 4, 6, 8, 10 and 14 weeks after starting treatment
Method of measurement
use of Vitiligo Extent Tensity Index (VETI) score

2

Description
Intensity of repigmentation
Timepoint
At the beginning of the study (before the intervention) and 2, 4, 6, 8, 10 and 14 weeks after starting treatment
Method of measurement
use of Vitiligo Extent Tensity Index (VETI) score

Secondary outcomes

1

Description
Treatment Tolerance
Timepoint
At the beginning of the study (before the intervention) and 2, 4, 6, 8, 10 and 14 weeks after starting treatment
Method of measurement
questionnaire (Scoring to pain from 0 to 10)

2

Description
therapeutic satisfaction
Timepoint
At the beginning of the study (before the intervention) and 2, 4, 6, 8, 10 and 14 weeks after starting treatment
Method of measurement
questionnaire (Scoring from 0 to 10)

Intervention groups

1

Description
Intervention group: We use 1-2 cc of Exir Pharmaceutical Company N-acetylcysteine 5% ampoule on the lesion and microneedle with NESOYA microneedling device until occurring the pinpoint bleeding, we continue the treatment sessions every two weeks up to 6 sessions and ask the patient a daily use of the combination drug N-acetylcysteine 4.7% (a combination of N-acetylcysteine powder 4.7 g and Eucerin 95.3 g) on the lesion for 2.5 months.
Category
Treatment - Drugs

2

Description
control group: We use 1-2 cc of placebo (5 cc distilled water of Caspian Pharmaceutical Company) on the lesion and microneedle it for 2 minutes with NESOYA microneedling device until occurring the pinpoint bleeding, we continue the treatment sessions every two weeks up to 6 sessions.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoole-Akram Hospital
Full name of responsible person
Elham Ziaeifar
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Rasoole - Akram Hospital, Maziyar Mansoori Sattarkhan Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Elham Ziaeifar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available