

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of suction blister and micro punch grafting methods in the treatment of patients with stable vitiligo

Protocol summary

Study aim

Comparison of suction blister and micro punch grafting methods in the treatment of patients with stable vitiligo

Design

Double-blind clinical trial work with random assignment

Settings and conduct

2019-2020/ Alzahra Hospital Dermatology Clinic

Participants/Inclusion and exclusion criteria

1- The age of patients should be between 13 and 65 years 2. Patients must give informed consent 3. Patients should be willing to cooperate during the study and follow-up period

Intervention groups

Punch graft- suction blister

Main outcome variables

Improvement-Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210206050270N1**

Registration date: **2021-07-21, 1400/04/30**

Registration timing: **retrospective**

Last update: **2021-07-21, 1400/04/30**

Update count: **0**

Registration date

2021-07-21, 1400/04/30

Registrant information

Name

Atefe Samimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3782 0132

Email address

atsamimi71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

2020-10-06, 1399/07/15

Actual recruitment end date

2020-10-21, 1399/07/30

Trial completion date

2021-05-20, 1400/02/30

Scientific title

Comparison of suction blister and micro punch grafting methods in the treatment of patients with stable vitiligo

Public title

Comparison of suction blister and micro punch grafting methods in the treatment of patients with stable vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with persistent vitiligo are resistant to medical treatment, ie they have not had a new lesion in the past year and their previous lesions have not become larger. Patients should be between 13 and 65 years old Patients must give informed consent Patients should be willing to cooperate during the study and follow-up period.

Exclusion criteria:

Patients with immunodeficiency atients with bleeding disorders Patients being treated for other illnesses

Age

From **13 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **31**

More than 1 sample in each individual

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

In each patient, 2 patches of vitiligo are selected in similar parts of the body or in symmetrical parts of the body

Actual sample size reached: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

In each patient, 2 vitiligo patches are selected in similar parts of the body or in symmetrical parts of the body. Then one of the patches is called A and the other B is called by the third person not involved in the study without the patient and the reader. The patch for each intervention will be selected using the online software Random.org so that the two letters A and B are entered in the software, then the letter that the software shows in the first row will indicate the patch that The suction blister on it and the second letter displayed will indicate the patch on which the micro punch grafting will be performed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No. 186, Farhang Complex, 6th Ave., Farhang Blvd.

City

Isfahan

Province

Isfahan

Postal code

8178644802

Approval date

2020-10-03, 1399/07/12

Ethics committee reference number

IR.MUI.MED.REC.1399.573

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Having Complaints

Timepoint

2 and 4 months after treatment

Method of measurement

questionnaire- visual analog scale (VAS)

2

Description

Improvement Score

Timepoint

2 and 4 months after treatment

Method of measurement

questionnaire-visual analog scale (VAS)

3

Description

Satisfaction Score

Timepoint

2 and 4 months after treatment

Method of measurement

questionnaire -visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Punch graft 1) Sterilize the graft site 2) The site will be anesthetized with topical lidocaine.3) Harvesting 100-200 2 mm punches in one or more stages 4) Graft implantation with 1.5 punch at the lesion site 5) Dressing the graft site with Vaseline gas 6) Remove the dressing a week later

Category

Treatment - Devices

2

Description

Intervention group: suction blister 1) Blisters on healthy

areas of the skin that cover areas of the body2) Sterilize the graft site3) The site will be anesthetized with topical lidocaine.4) A vesicle is then formed at the donor site using the device described by Gupta et al.5) At this stage, the vitiligo patch is prepared and the dermis is removed on it by a dermabrator at an average speed of 15,000 rpm until the bleeding spots related to the papillary dermis appear. The blister created is then placed on a glass slide separated by special scissors and carefully placed on the patch.6) The lesion is then bandaged.7) Remove the dressing a week later

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital Dermatology Clinic

Full name of responsible person

Atefe Samimi

Street address

Isfahan university of medical science, Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

atsamimi71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

atsamimi71@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of medical sciences, Hezar jerib street

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

international@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

50

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

Esfahan University of Medical Sciences

Full name of responsible person

Atefe Samimi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.186, Farhang Complex, 6th Ave, Shafagh Blv,

City

Esfahan

Province

Isfahan

Postal code

685311654

Phone

+98 31 3782 0132

Fax**Email**

atsamimi71@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Atefe Samimi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.186, Farhang Complex, 6th Ave, Shafagh Blv,

City

Esfahan

Province

Isfahan

Postal code

8565121654

Phone

+98 31 3782 0132

Fax**Email**

atsamimi71@gmail.com

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

Esfahan University of Medical Sciences

Full name of responsible person

Atefe Samimi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.186, Farhang Complex, 6th Ave, Shafagh Blv,

City

Esfahan

Province

Isfahan

Postal code

658511654

Phone

+98 31 3782 0132

Fax**Email**

atsamimi71@gmail.com

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