

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effects of transplantation (non-cultured autologous melanocytes) bulge region , dermal papilla and outer root sheet in stable vitiligo plaques.

Protocol summary

Summary

This is a randomized, double-blind, controlled clinical trial with placebo. The main objective is: determination of bulge and dermal papilla repigmentation of the bonding and the outer root sheet of stable plaque. Criteria for inclusion: 1) At least 4 years have passed since the onset of their disease. 2) At least 6 months of stable disease and no new lesions. 3) The patient's lesions are bilateral. 4) There is not an appropriate response to other therapies. 5) There is no history of disease such as: hypothyroidism, hyperthyroidism, diabetes, asthma, atopic dermatitis, rhinitis, psoriasis, ulcerative colitis, lupus, alopecia areata, anemia pernicious. 6) Not currently being treated with other methods. Exclusion criteria: 1) pregnant women. 2) The incidence of these diseases 3) Parts of the bodies that are routinely exposed to light. 4) Patients who once responded to NB-UVB return is after the break. 5) Keloid. At first a small areas of the head selected, after anesthesia by lidocaine and epinephrine is then using a punch mm5 hair in the area occipital, removed and the bulge and outer root sheet dermal papilla may be extracted by suspension of the 3 is injected into the area provided below. Scheme used in this study, a block design capacity is 3 for each block. The patient in this study is considered a block and a third treatment is performed on each patient. Block designs, random allocation of treatments in each block must be done. Plaque in the first two of which will be created later Abryshn dermal needles are traumatized. A - The main area where melanocytes dermal papilla and outer Root sheet plus the Bulge area into the area. B - With the other, just insert a needle to create and respond to trauma is trauma. C - With the other, as seen in the control and the treatment will not be around either. Patients every month (up to 6 months) will follow-up. In each session, the size of the lesion on both sides will be measured and photographed and the response rates to treatment by a doctor who do not participate in the study based on the

recovery rate subdivided from 95 to 100% = excellent, and 65 - 94% = Good, and 25 - 64% Fair = and 0 - 24% = Poor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203108567N1**

Registration date: **2012-03-10, 1390/12/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-10, 1390/12/20

Registrant information

Name

Parviz Toossi

Name of organization / entity

Department of Dermatology, Skin Research Center
Shahid Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 1507

Email address

src@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Skin Research Center, Shahid Beheshti University of
Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of transplantation (non-cultured autologous melanocytes) bulge region , dermal papilla and outer root sheet in stable vitiligo plaques.

Public title

Effects of transplantation (non-cultured autologous melanocytes) in stable vitiligo plaques.

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for inclusion: 1) At least 4 years have passed since the onset of their disease. 2) at least 6 months of stable disease and no new lesions. 3) The patient's lesions are bilateral.symetric 4) There is not an appropriate response to other therapies. 5) There is no history of disease. Such as hypothyroidism, hyperthyroidism, diabetes, asthma, atopic dermatitis, rhinitis, psoriasis, ulcerative colitis, lupus, alopecia areata, anemia Pernisious ... 6) not currently being treated with other methods. Exclusion criteria: 1) pregnant women. 2) The incidence of these diseases 3) parts of the body that are routinely exposed to light. 4) patients who once responded to NB-UVB return is after the break. 5) keloid

AgeFrom **20 years** old to **55 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **10****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Skin Research Center Ethics Committee

Street address

Shohada hospital, Shahr-dari St.,Tajrish Sq.

City

Tehran

Postal code

198993414

Approval date

2011-02-27, 1389/12/08

Ethics committee reference number

89- 941 م م ت

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

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

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

Repigmentation

Timepoint

One month

Method of measurement

Size and photo

Secondary outcomes**1****Description**

Side effect

Timepoint

During study

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group: initially a small areas of the head selected by lidocaine with epinephrine anesthetic is then using a punch mm5 in the area occipital removed and the bulge and outer root sheet and dermal papilla may be extracted by suspension of the procurement 3 is injected into the area.Scheme used in this study, a block design capacity is 3 for each block. The patient in this study, is considered a block and a third treatment is performed on each patient. Block designs, random allocation of treatments in each block must be done.

Plaque in the first two of which will be created later dermal ablation with needle are traumatized. a - The main area where melanocytes Dermal papilla and outer Root sheet plus the Bulge area into the area.

Category

Treatment - Surgery

2

Description

C - with the other, as seen in the control and the treatment will not be around either.

Category

N/A

3

Description

B - with the other, just insert a needle to create trauma and respond to trauma

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish & Loghman hospitals

Full name of responsible person

Dr. Shakoei

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossien Goodarzi

Street address

Chamran Highway St. Evin Taleghani Hospital Medical School, 3rd Floor

City

Tehran

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, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dermatology Research Center

Full name of responsible person

Dr. Shakoei

Position

MD, Dermatology Resident

Other areas of specialty/work

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Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty