# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 regimentation 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 NBUVB return is after the break. 5) Kelloid. 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 leions. 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, ulceritive 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 NBUVB return is after the break. 5) kelloid
**Age**
From **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, Shahrdari St.,Tajrish Sq.
**City**
Tehran
**Postal code**
198993414
**Approval date**
2011-02-27, 1389/12/08
**Ethics committee reference number**
م م ت941 -89

## 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 occuipital 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 abration 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 traumaand 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 HighwaySt. 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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## Person responsible for scientific inquiries

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Dr.Toosi

**Position**

Professor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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**Web page address**

## 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*