

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison Study of efficacy of basal cell layer suspension and topical calcipotriol with basal layer suspension in Treatment of Stable Vitiligo

#### Protocol summary

##### Summary

This study is designed to compare the efficacy of basal cell layer suspension and topical calcipotriol with basal layer suspension in Treatment of Stable Vitiligo. 20 patients as groups of 10 subjects will be enrolled from the patients referred to dermatology clinic with a diagnosis of vitiligo. The main Inclusion criteria is : age (between 13 and 60 years), leukoderma type, stable vitiligo and lack of response to common treatment . The exclusion criteria is : patients with cardiovascular disorders ; patients older than 60 years and patients under 13 years old and patients with history of hypertrophic scar tissue and colloid. Skin samples taken from normal skin will be sent to laboratory for isolation of basal cell suspension. The suspension will be injected to the affected areas which will be dermabrasion formerly. In the second group, the calcipotriol cream will be used additionally. After recovery of the injection site in the second group, calcipotriol will be used once daily up to 6 months. The two groups will be compared in terms of pigmentation improvement.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014071418373N1**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-04, 1393/05/13

##### Registrant information

##### Name

Mohamad Reza Ranjkesh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 116 5061

##### Email address

ranjkeshm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Umbilical Cord Stem Cell Research Center, Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2015-04-21, 1394/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison Study of efficacy of basal cell layer suspension and topical calcipotriol with basal layer suspension in Treatment of Stable Vitiligo

##### Public title

Comparison Study of efficacy of skin pigment cell graft and topical calcipotriol cream with skin pigment cell graft in Treatment of Vitiligo

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with 13 to 60 years old ; The number and size of lesions in at least two areas ; Leukoderma type ; stable vitiligo ; Lack of response to common treatment ; Consent to participate in the study.

Exclusion criteria: The patients who have responded well to the treatment ; Patients with cardiovascular disorders ; People aged over 60 years ; Pregnant and lactating women ; Patients under 13 years old ; Patient with history of Koebner phenomenon ; Patient with history of hypertrophic scar tissue and colloid ; The patients with unstable vitiligo.

**Age**

From **13 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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 Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Daneshgah Sq.

**City**

Tabriz

**Postal code****Approval date**

2014-03-08, 1392/12/17

**Ethics committee reference number**

92228

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

Vitiligo

**ICD-10 code**

L80

**ICD-10 code description**

Vitiligo

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

Pigmentation of skin with epidermal basal cell suspension grafting in the treatment of stable vitiligo

**Timepoint**

Baseline, after recovering of injection site and then monthly for 6 months

**Method of measurement**

Clinical observation

**2****Description**

Pigmentation of skin with epidermal basal cell suspension grafting and Calcipotriol in the treatment of stable vitiligo.

**Timepoint**

Baseline, after recovering of injection site and then monthly for 6 months

**Method of measurement**

Clinical observation

**Secondary outcomes**

empty

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

In the first group : Epidermal basal cell suspension will inject in the dermabraded affected areas of Vitiligo, then grafted area will dress up by a tour of silicon covered with a layer of woven gauze moistened with saline compressed and covered with semi-permeable Tegaderm film. The dressing is removed after 8 days. After 6 months, the amount and quality of depigmentation of grafted area will be studied and compared with second group. To determine the recovery rate serial images will produce monthly and repigmentation will express as percentage.

**Category**

Treatment - Other

**2****Description**

In the second group :1 to 3 weeks after basal cell suspensions transplantation when wound healing is complete, Calcipotriol will be applied topically once a day for 6 months and then the quality of repigmentation will be discussed. To determine the recovery rate serial images will produce monthly and repigmentation will express as percentage

**Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Dermatology Clinic of Sina Hospital

**Full name of responsible person**

Behzad Anosh

**Street address**

Dermatology ward, Sina Hospital, Azadi Ave.

**City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Umbilical Cord Stem Cell Research Center of Tabriz  
University of Medical Sciences

**Full name of responsible person**

Samira Molayi

**Street address**

Tabriz University of Medical Sciences, Daneshgah  
Ave, Emam Reza hospital, Umbilical Cord Stem Cell  
Research Center (UCSRC) building.

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Umbilical Cord Stem Cell Research Center of Tabriz  
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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Behzad Anosh

**Position**

Resident of Dermatology

**Other areas of specialty/work**

**Street address**

Dermatology ward, Sina Hospital, Azadi Ave

**City**

Tabriz

**Postal code**

**Phone**

00

**Fax**

**Email**

behzadanosh@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohamad Reza Ranjkesh

**Position**

Dermatologist/Assistant professor

**Other areas of specialty/work**

**Street address**

Dermatology ward, Sina Hospital, Azadi Ave.

**City**

Tabriz

**Postal code**

**Phone**

+98 41154121013

**Fax**

**Email**

ranjkeshm@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Behzad Izadseresht

**Position**

Medical Student

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

00

**Fax**

**Email**

b.izadseresht@yahoo.com

**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*