

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Ranjesh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 116 5061

Email address

ranjeshm@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