Clinical Trial Protocol
Iranian Registry of Clinical Trials
22 Feb 2022

Efficacy of autologous non-cultured and non-trypsinised melanocytes and keratinocytes grafting in treatment of refractory vitiligo

Protocol summary

Study aim
To assess the efficacy of autologous, non-cultured and non-trypsinized melanocyte transplantation in treatment of stable vitiligo

Design
This phase 3 study is performed in 93 vitiligenous lesions at single center in vitiligo patients who refer to single center of Haj daie dermatology clinic in Kermanshah city. Information about this procedure is given to the patients and after obtaining consent enroll in study.

Settings and conduct
Vitiligo is a common dermatology disorder that usually unresponsive to medical therapy and associated with unpleasant appearance, familial problems and neuropsychiatric disorder. The donor site containing normal pigmentation such as buttock and thigh area is selected. After local anesthiesia, firstly the epidermis is shaved using a curette number 2 until point bleeding appears as a marker of the epidermis and dermis junction, later harvested material is mixed with some hyaluronic acid gel in a sterile container and finally this suspension transplanted in recipient denuded sites. This site is dressed with semi-permeable dressing. The patient is evaluated at the first and third week and then monthly. The rate of re-pigmentation and possible complications are recorded.

Participants/Inclusion and exclusion criteria
Patients who clinically confirmed stable vitiligo are subjected to treatment. Pregnant and breast feeding women, patients with cardio-vascular and repair disorder, unstable and universal vitiligo rule out from study.

Intervention groups
Because of absence of melanocyte reservoir in vitiligenous lesions most of vitiligo unresponsive to ordinary treatment and phototherapy. Autologous, non-cultured and non-trypsinized melanocyte transplantation is a safe and less aggressive procedure that can be an appropriate method for treatment of refractory vitiligo.

Main outcome variables
The rate of re-pigmentation in treated area

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20110507006403N9
Registration date: 2020-03-16, 1398/12/26
Registration timing: registered_while_recruiting

Last update: 2020-03-16, 1398/12/26
Update count: 0
Registration date
2020-03-16, 1398/12/26

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-19, 1398/11/30
Expected recruitment end date
2020-06-19, 1399/03/30
Actual recruitment start date
empty
Actual recruitment end date
Scientific title
Efficacy of autologous non-cultured and non-trypsinised melanocytes and keratinocytes grafting in treatment of refractory vitiligo

Public title
Efficacy of autologous and non-processed melanocyte grafting in treatment of vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinically documented vitiligenous lesions

Exclusion criteria:
Unstable vitiligo Pregnancy Breast feeding Generalized vitiligo Patients recently subject to phototherapy and drugs used for vitiligo Cardio-vascular patients Patients with repair disorder

Age
From 15 years old to 60 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 20
More than 1 sample in each individual
Number of samples in each individual: 5
Patients usually have more than one lesion.

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
ethics committee of Kermanshah University of Medical Sciences
Street address
mostafa emami Ave., kermanshah city,
City
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Province
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Postal code
6715847141
Approval date
2020-01-14, 1398/10/24
Ethics committee reference number
IR.KUMS.REC.1398.975

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Ethics committee reference number
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Ethics committee
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Health conditions studied

1
Description of health condition studied
Vitiligo
ICD-10 code
L80
ICD-10 code description
Vitiligo

Primary outcomes
Description
Re-pigmentation

Timepoint
The first and third week and then every month for up to 4 months

Method of measurement
Area measurement with software

Secondary outcomes
empty

Intervention groups

Description
The epidermis is shaved from the lower limb as donor site, which has normal pigment with a disposable and sharp curettage device. The harvested materials is mixed with hyaluronic acid gel. The vitiligo skin patches as recipient site, also is shaved with curettage. Later the harvested suspension is transplanted in the recipient site. The patient is evaluated at the first and third week and then monthly.

Category
Treatment - Surgery

Recruitment centers

Recruitment center
Name of recruitment center
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Full name of responsible person
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Grant name
Grant code / Reference number
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan
Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available