The efficacy of Needling as an adjuvant to Narrowband Ultraviolet B therapy in treatment of patients with stable vitiligo referred to dermatology clinic of Shohada e Tajrish hospital

Protocol summary

Summary
Aim: To determine the efficacy and toleribility of repeated needling combined with NBUVB therapy in treatment of generalized, stable, refractory vitiligo.

Design: 12 weeks prospective, single-centre, before-after, clinical trial

Inclusion criteria: Stable vitiligo for at least 2 years

Exclusion criteria: Pregnancy; breastfeeding; photosensitivity; tendency to form keloid or hypertrophic scar; history of skin cancer; immunosuppression; xeroderma pigmentosum; systemic lupus erythematosus; porphyrias; autoimmune disorders; coagulopathies

Study population: Twenty-six cases of intractable stable vitiligo from Dermatology Outpatient Clinic at Shohada-e-Tajrish hospital

Interventions: After local infiltration of lidocaine, the pigmented skin at the periphery of the lesion will be pricked with 30 G needle and will be drived toward depigmented patch, near dermo-epidermal junction, to push melanocytes from pigmented area to the depigmented sites. Needling will be done once a week for 12 weeks. All the patients will receive additive NBUVB (311 ± 2 nm) therapy with initial dose of 50mj/cm2 three times a week. Doses of NBUVB will be increased 50mj/cm2 per session until the maximum dose reach to 2000mj/cm2 then the same dose will be continued. Study time: During September-December 2010

Primary outcome: Calculation of the percentage of repigmentation will be done with AutoCAD and ImageJ softwares via analysis of the patient's photos at the baseline and weeks 4, 8 and 12. Tolerability will be evaluated by recording adverse events (erythema, pain, pruritus, scaling/dryness, erosion/crusting, scar, koebner phenomenon, post inflammatory hyper/hypo pigmentation) on a 5-point scale from 0 (none) to 4 (severe) by the investigator at each visit.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201112268273N2
Registration date: 2012-03-19, 1390/12/29
Registration timing: retrospective

Last update:
Update count: 0
Registration date
2012-03-19, 1390/12/29

Registrant information
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Atyeh Ebadi
Name of organization / entity
Skin Research Center, Shahid Beheshti Medical university
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source
Skin Research Center of Shahid Beheshti University of Medical Sciences

Expected recruitment start date
2011-04-01, 1390/01/12

Expected recruitment end date
2011-09-01, 1390/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of Needling as an adjuvant to Narrowband Ultraviolet B therapy in treatment of patients with stable vitiligo referred to dermatology clinic of Shohada e Tajrish hospital

Public title
Efficacy of Needling in treatment of vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: stable vitiligo for at least 2 years
Exclusion criteria: age < 18 years old; a history of pregnancy; breastfeeding; photosensitivity; history of skin cancer; immunosuppression; tendency to form keloid or hypertrophic scar; xeroderma pigmentosum; systemic lupus erythematosus; porphyries; autoimmune disorders; coagulopathies

Age
From 18 years old to 60 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 26

Randomization (investigator's opinion)
Not randomized

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 Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Velenjak District

City
Tehran

Postal code

Approval date
2011-02-27, 1389/12/08

Ethics committee reference number
941 پ/ت/م

Health conditions studied

1

Description of health condition studied
Vitiligo

ICD-10 code
L 80

ICD-10 code description

Primary outcomes

1

Description
repigmentation

Timepoint
at 4, 8 and 12 weeks in comparison with baseline

Method of measurement
AutoCAD (Autodesk Inc., San Rafael, CA, USA) and ImageJ (National Institute of Health, USA) software

Secondary outcomes

1

Description
patient's demographic data

Timepoint
at baseline

Method of measurement
Inquiry form

Intervention groups

1

Description
After local infiltration of lidocaine, the pigmented skin at the periphery of the lesion will be pricked with 30 G needle and will be driven toward depigmented patch, near dermo-epidermal junction, to push melanocytes from pigmented area to the depigmented sites. Needling will be done at baseline (week 0) followed by once a week for 12 weeks. All the patients will receive additive NBUVB (311 ± 2 nm) therapy with initial dose of 50mj/cm2 three times a week. Doses of NBUVB will be increased 50mj/cm2 per session until the maximum dose reach to 2000mj/cm2 then the same dose will be continued.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
dermatology outpatient clinic of Shohada e Tajrish hospital

Full name of responsible person
Dr Fariba Ghalamkarpour

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Skin Research Center of Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Parviz Tousi

Street address
Skin Research Center of Shahid Beheshti University of Medical Sciences, Shohada e Tajrish hospital, Tajrish Sq, Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Skin Research Center of 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
Skin Research Center of Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Fariba Ghalamkarpour

Position
Associated professor

Other areas of specialty/work

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Person responsible for updating data

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Atyeh Ebadi

Position
Resident of dermatology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
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