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 tolerability 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; coagopathies

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
Name
Atyeh Ebadi
Name of organization / entity
Skin Research Center, Shahid Beheshti Medical university
Country
Iran (Islamic Republic of)
Phone
+98 21 2274 4392
Email address
atyeh_ebadi@sbmu.ac.ir

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; coagolopathies

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
Tolerability

Timepoint
at 4, 8 and 12 weeks in comparison with baseline( week
0)

Method of measurement
scale form that will be filled by physician

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 drived 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

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**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**
empty

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**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**

**Street address**
Skin research center of Shahid Beheshti University of Medical Sciences, Shohada e Tajrish hospital, Tajrish Sq, Tehran, Iran

**City**
Tehran

**Postal code**

**Phone**
+98 21227741507

**Fax**

**Email**
fghalamkarpour@yahoo.com

**Web page address**

---

**Person responsible for scientific 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**

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

**City**
Tehran

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**Phone**
+98 21227741507

**Fax**

**Email**
fghalamkarpour@yahoo.com

**Web page address**

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**Person responsible for updating data**

**Contact**

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

**Full name of responsible person**
Atyeh Ebadi

**Position**
resident of dermatology

**Other areas of specialty/work**

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

**City**

**Postal code**

**Phone**
+98 21227741507

**Fax**

**Email**
aty_ebadi@yahoo.com

**Web page address**

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**Sharing plan**

Deidentified Individual Participant Data Set (IPD)
empty