Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Apr 2020

308-nm excimer laser plus topical calcipotriol in the treatment of vitiligo

Protocol summary

Summary
There is a large variety of therapeutic agents for the treatment of vitiligo but it still remains a challenge. Narrow-band UVB phototherapy and 308-nm excimer laser have been shown to be safe and effective for the treatment of vitiligo. Topical calcipotriol has recently been reported to enhance the efficacy of phototherapy especially 8-methoxypsoralen plus UVA (PUVA). The goal of this study was to evaluate whether the addition of topical calcipotriol enhances the efficacy of 308-nm excimer laser in the treatment of vitiligo. The patients with vitiligo with bilateral symmetrical lesions will enter in this controlled prospective, right/left comparative, single blinded clinical trial, over a 24-month period. They will be divided into two groups, intervention and control randomly. All patients in two groups will receive 308-nm excimer laser therapy on the lesions of the right side of the body, two times weekly for 12 weeks. Calcipotriol ointment (Daivonex®) will be added to 308-nm excimer laser on the right side of the patients in the intervention group twice daily. Vaseline will be applied by the control group on the both sides and by the intervention group on the left side. It will be taken the photos from the all of the lesions in both groups at the first and the last visit and finally with the Visual scale software, the rate of repigmentation will be determined and so response to each therapeutic strategy can be compared.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138808212704N1
Registration date: 2010-12-02, 1389/09/11
Registration timing: retrospective

Recruitment status
Recruitment complete
Funding source
Vice-chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date
2007-05-09, 1386/02/19
Expected recruitment end date
2009-05-09, 1388/02/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
308-nm excimer laser plus topical calcipotriol in the treatment of vitiligo

Public title
308-nm excimer laser plus topical calcipotriol in the treatment of vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: The patients that suffer from localized or generalized vitiligo at least for one year or stable vitiligo, All the phenotypes of skin color. Exclusion criterion: Pregnancy, Lactation, Allergy to calcipotriol, Renalinsufficiency, Abnormality in bone or calcium metabolism, Light-sensitive dermatoses, Photodermatoses, Phototoxic systemic or topical medication, Previous history of arsenic exposure, Excessive exposure to UV light, Previous history of skin cancer.

Age
From 18 years old

Gender
Both
Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description


Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor for Research of Tehran University of Medical Sciences

Street address

Vice-chancellor for Research of Tehran University of Medical Sciences, 205th room, 1st floor, Education Bldg., Poursina st

City

Tehran

Postal code

1417613151

Approval date

2007-05-09, 1386/02/19

Ethics committee reference number

20449

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Repigmentation

Timepoint

first visit, 12 weeks after starting therapy

Method of measurement

Visual scale software

Secondary outcomes

1

Description

irritant contact dermatitis

Timepoint

2 times per week (in each phototherapy session)

Method of measurement

clinical examination

Intervention groups

1

Description

308-nm excimer laser two times weekly for 12 weeks plus Calcipotriol ointment (Daivonex®) twice daily

Category

Treatment - Drugs

2

Description

308-nm excimer laser two times weekly for 12 week plus Vaseline twice daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Somayeh Khezri

Street address

Razi Hospital, Vahdat_e_eslami st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research department of medical school of Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhound Zadeh

Street address

Research department of medical school of Tehran University of Medical Sciences, 205th room, 1st floor, Education Bldg., Poursina st.

City
### Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research department of medical school of Tehran 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**
  - Razi Hospital
- **Full name of responsible person**
  - Somayeh Khezri
- **Position**
  - Resident of dermatology

**Other areas of specialty/work**

Street address

- Razi Hospital, Vahdat_e_eslami st.
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1199663911

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khezri@razi.tums.ac.ir

**Web page address**

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**Person responsible for updating data**

Contact

- **Name of organization / entity**
  - Razi Hospital
- **Full name of responsible person**
  - Hassan Seirafi
- **Position**
  - Associate Professor of Dermatology

**Other areas of specialty/work**

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**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