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

Registrant information
Name
Somayeh Khezri
Name of organization / entity
Razi hospital
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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,
Renal insufficiency, 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

**Blinding (investigator's opinion)**
- Single blinded

**Placebo**
- Used

**Assignment**
- Parallel

**Secondary 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

**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**
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
empty
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
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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