Evaluation of Safety and efficacy of hydrogen peroxide 35% topical solution, in Comparison with cryotherapy in on treatment of patients with senile lentigo

Protocol summary

Study aim

Design
A clinical trial without a control group, with parallel, not blinded, randomized groups

Settings and conduct
After obtaining the necessary authorization for the project, 33 patients with senile lentigo referred to Loghman Hakim and Martyrs Tajrish hospitals during the years 1976-97 are included in the study. After explaining the procedure and obtaining written informed consent from patients, we apply 35% hydrogen proxide topically on a lentigo pad with a cotton swab and allow the drug to remain in the area for 15 to 20 minutes. It is washed off 6 hours after taking the drug-soaked area. In the cryotherapy recipient group, the liquid nitrogen is applied to the lentigo surface by a cotton swab and allowed to remain in the area for 3 to 5 seconds.

Participants/inclusion and exclusion criteria
Inclusion criteria : They are over 16 years old, Do not meet the exclusion criteria, Have an informed consent to participate in the study Exclusion criteria: Person with Fitzpatrick skin type V, People with drug allergies, Under 16 years, I am pregnant or nursing, People who have used other treatments in the last 4 weeks to eliminate lentigo (such as cryotherapy or imaging modality ointment), Vitiligo patients

Intervention groups
In each patient, hydrogen proxide and cryotherapy are used to treat lesions on one side of the body randomly.

Main outcome variables
Age; Sex; Fitzpatrick skin type ; Duration of illness; Number of lesions; lesion site; Previous treatment history; Recurrence history following previous treatment; Recurrence rate; Dosage; Effectiveness of the drug; Severity of drug side effects; Recurrence after treatment;

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20190519043632N1
Registration date: 2019-10-02, 1398/07/10
Registration timing: registered_while_recruiting

Last update: 2019-10-02, 1398/07/10
Update count: 0

Registration date
2019-10-02, 1398/07/10

Registrant information
Name
Fahime Salehi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4430 0796
Email address
fahime.salehi@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-07-21, 1398/04/30
Expected recruitment end date
2021-03-20, 1399/12/30
Actual recruitment start date
empty
Evaluation of Safety and efficacy of hydrogen peroxide 35% topical solution, in Comparision with cryotherapy in on treatment of patients with senile lentigo

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People with Fitzpatrick skin type 1-4 People without a history of drug allergy Age over 16 years No pregnancy or lactation Failure to receive other treatments to eliminate lentigo in the last 6 weeks (such as cryotherapy or imiquimod ointment) No Vitiligo

Exclusion criteria:
Age
From 16 years old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 33

Randomization (investigator's opinion)
Randomized

Randomization description
In each patient, hydrogen proxide and cryotherapy are used to treat lesions on one side of the body randomly. Patients are randomly assigned to receive two envelopes, one on the left and one on the other, and two on paper, and the patient randomly selects one from each envelope.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

Ethics committee
Name of ethics committee
Ethics committee of Shahid beheshti University of Medical Sciences

Street address
Shahid Chamran Square, Yemeni Street, Shahid Beheshti University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1983969411

Approval date
2019-04-14, 1398/01/25

Ethics committee reference number
Ir.sbmu.src.rec.1398.001

Health conditions studied

Description of health condition studied
senile lentigo

ICD-10 code

ICD-10 code description

Primary outcomes

Description
Effectiveness of the drug

Timepoint
One week, three weeks and three months

Method of measurement
Physical examination

Secondary outcomes
empty

Intervention groups

Description
Intervention group 1: Apply 35% hydrogen proxide topically with a cotton swab on the lentigo surface and allow the medication to remain in the area for 15 to 20 minutes to dry. Be.

Category
Treatment - Drugs

Description
Intervention group 2: In the cryotherapy recipient group, liquid nitrogen is applied to the surface of the lentigo by a cotton swab and allowed to remain in the area for 3 to
5 seconds.

**Category**
Treatment - Drugs

## Recruitment centers

1. **Recruitment center**
   - **Name of recruitment center**: Shohada-e-Tajrish
   - **Full name of responsible person**: Fahimeh Salehi najaf abadi
   - **Street address**: Tajrish Square, Tajrish Shohada Hospital

### Sponsors / Funding sources

1. **Sponsor**
   - **Name of organization / entity**: Shahid Beheshti University of Medical Sciences
   - **Full name of responsible person**: Afshin zarghi
   - **Street address**: Shahid Chamran Zargra - Yemeni St - Shahid Beheshti University of Medical Sciences-Headquarters 2- floor 5- Vice chancellor for research and technology - Shahid Beheshti University of Medical Sciences

### Person responsible for general inquiries

**Contact**
- **Name of organization / entity**: Shahid Beheshti University of Medical Sciences
- **Full name of responsible person**: Fahimeh Salehi najaf abadi
- **Position**: Resident
- **Latest degree**: Medical doctor
- **Other areas of specialty/work**: Dermatology

- **Street address**: shahran, Second Circle, No. 148, Unit 5
- **City**: Tehran
- **Province**: Tehran
- **Postal code**: 1989934148
- **Phone**: +98 21 25719
- **Fax**: +98 21 2271 9014
- **Email**: pr_shohada@sbmu.ac.ir

### Person responsible for scientific inquiries

**Contact**
- **Name of organization / entity**: Shahid Beheshti University of Medical Sciences
- **Full name of responsible person**: Fahimeh Salehi najaf abadi
- **Position**: Resident
- **Latest degree**: Medical doctor
- **Other areas of specialty/work**: Dermatology

- **Street address**: shahran, Second Circle, No. 148, Unit 5
- **City**: Tehran
- **Province**: Tehran
- **Postal code**: 1989934148
- **Phone**: +98 21 25719
- **Fax**: +98 21 2271 9014
- **Email**: pr_shohada@sbmu.ac.ir

### Grant details

- **Title of funding source**: Shahid Beheshti University of Medical Sciences
- **Proportion provided by this source**: 100
- **Public or private sector**: Public
- **Domestic or foreign origin**: Domestic
- **Category of foreign source of funding**: empty
- **Country of origin**: empty
- **Type of organization providing the funding**: Academic
Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fahimeh Salehi najaf abadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
shahrani, Second Circle, No. 148, Unit 5
City
Tehran
Province
Tehran
Postal code
1478853539
Phone
+98 21 4430 0796

Email
fahime.salehi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available