

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

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

Protocol summary

Study aim

Evaluation of Safety and efficacy of hydrogen peroxide 35% topical solution, in Comparision to cryotherapy in on treatment of patients with senile lentigo referring to Shohada-e-Tajrish and Loghman-e-Hakim hospital in 1397-98.

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

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Evaluation of Safety and efficacy of hydrogen peroxide 35% topical solution, in Comparision to cryotherapy in on treatment of patients with senile lentigo referring to Shohada-e-Tajrish and Loghman-e-Hakim hospital in 1397-98.

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**1****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

lr.sbm.u.src.rec.1398.001

Health conditions studied**1****Description of health condition studied**

senile lentigo

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Effectiveness of the drug

Timepoint

One week, three weeks and three months

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups**1****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

2**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

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Web page address

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
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Grant name

Grant code / Reference number

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

Yes

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

Type of organization providing the funding

Academic

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

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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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