Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Ir.sbmu.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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Tehran

Province
Tehran

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pr_shohada@sbmu.ac.ir

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 5- Vice chancellor for research and technology - Shahid Beheshti University of Medical Sciences

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Mpajouhesh@sbmu.ac.ir

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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Person responsible for scientific inquiries

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Person responsible for updating data

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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