Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Determination and comparison of the effect of Oxybutynin in two forms of gel and nanoemulgel versus placebo in people with primary palmar hyperhidrosis

Protocol summary

Study aim
Evaluation of the local effect of Oxybutynin in two forms of gel and nanoemulgel in treatment of primary palmar hyperhidrosis

Design
Phase 3, parallel group, clinical trial, with consecutive sampling, including 30 patients, double blinded, computerized randomized with permuted blocks

Settings and conduct
The study is conducted in dermatology clinic of Shiraz University of Medical Sciences. Patients are devided into two groups A and B. (each group has 15 members) In group A, patients are randomly assigned to be treated with 1% topical Oxybutynin gel on one side and placebo on the other. In group B, patients are randomly assigned to be treated with 1% topical Oxybutynin nanoemulgel on one side and placebo on the other. All drugs are packed in similar tubes. Topical medications are applied twice daily for a month. Patients are assessed once at the beginning of the study and one time after one month of applying medications and will complete questionnaire related to the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Older than 18 years of age patients with primary palmar hyperhidrosis Exclusion criteria: Using any topical drugs that can affect palmar hyperhidrosis since one month before beginning of the research, Butox injection 3 month before beginning of the research, Pregnancy, Lactation, Hypersensitivity to the research drug

Intervention groups
Intervention group: Oxybutynin gel or nanoemulgel is applied twice daily on the palmar surface of one hand Control group: Gel base as the placebo on the palmar surface of the other hand

Main outcome variables
hyperhidrosis Disease Severity Scale(HDSS) Dermatology Life Quality Index(DLQI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210822052255N1**
Registration date: **2021-09-28, 1400/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-28, 1400/07/06**
Update count: **0**

Registration date
2021-09-28, 1400/07/06

Registrant information

Name
Najmeh Shakouri

Name of organization / entity

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Iran (Islamic Republic of)

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+98 71 3631 3937

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determination and comparison of the effect of Oxybutynin in two forms of gel and nanoemulgel versus placebo in people with primary palmar hyperhidrosis

Public title
Evaluation of local effect of Oxybutynin in treatment of palmar hyperhidrosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Older than 18 years of age patients with primary palmar hyperhidrosis Patients should have ability to understand Persian language of written consent and questionnaire to participate in the study All topical and oral treatments should be discontinued for at least 4 weeks before beginning of the study, except for Botox injections, which should not have been injected in the past 12 weeks.

Exclusion criteria:
Reluctance to cooperate Hypersensitivity to topical Oxybutynin Pregnancy and lactation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
One sample containing the Oxybutynin gel and the other sample containing gel base as the placebo.

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method was used for the two intervention groups and simple randomization method was used to choose the drug and placebo (left and right hand in each patient). A randomization table has been used for this purpose. The randomization table is attached to the proposal. Intergroup comparison between two intervention groups and intragroup comparison between each comparison group with its control group will be done. The advantage of using control group in each sample (intragroup comparison) in addition to reducing the sample size, is eliminating intergroup changes and thus increasing the accuracy of the comparison.

Blinding (investigator's opinion)
Double blinded

Blinding description
The tubes containing Oxybutynin gel and placebo are identical and coded. The tubes allocated to each patient are labelled with the same patients of patient recruitment number. Care providor and investigator that deliver the gels are not involved in the outcome assessment. Type of drugs and which hand is being treated and which one is selected as the control remains unclear for both the patient and the outcome assessor until the end of the study. Therefore the research will be double-blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz University of medical science, Zand Ave.

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2021-06-30, 1400/04/09

Ethics committee reference number
IR.SUMS.MED.REC.1400.195

Health conditions studied

1

Description of health condition studied
Primary palmar hyperhidrosis

ICD-10 code
L74.512

ICD-10 code description
Primary focal hyperhidrosis, palms

Primary outcomes

1

Description
Hyperhidrosis Disease Severity Index (HDSS)

Timepoint
Before intervention and one month after starting intervention

Method of measurement

Hyperhidrosis Disease Severity Index (HDSS) score formula

Secondary outcomes

1

Description
Dermatology Life Quality Index (DLQI)
Timepoint
Before intervention and one month after starting intervention
Method of measurement
Dermatology Life Quality Index (DLQI) formula score

Intervention groups

1

Description
Intervention group1: Simple 1% Oxybutynin gel is applied twice a day on the palm of a patient's hand for a month. Once at the beginning of the study and also after one month of taking the drug, the patient is visited. The drug is made by Dr. Ŝhohreh Alipour, a Pharmacologist colleague, PhD of Pharmaceutical Sciences, in the Pharmaceutics Laboratory of School of Pharmacy, Shiraz university of Medical Sciences.
Category
Treatment - Drugs

2

Description
Intervention group2: 1% Oxybutynin nanoemulgel is applied twice a day on the palm of a patient's hand for a month. Once at the beginning of the study and also after one month of taking the drug, the patient is visited. The drug is made by Dr. Ŝhohreh Alipour, a Pharmacologist colleague, PhD of Pharmaceutical Sciences, in the Pharmaceutics Laboratory of School of Pharmacy, Shiraz university of Medical Sciences.
Category
Treatment - Drugs

3

Description
Control group1: Gel base as the placebo is applied twice a day on the palm of the other patient's hand in both groups for a month. Once at the beginning of the study and also after one month of taking the drug, the patient is visited. The drug is made by Dr. Ŝhohreh Alipour, a Pharmacologist colleague, PhD of Pharmaceutical Sciences, in the Pharmaceutics Laboratory of School of Pharmacy, Shiraz university of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology clinic, Shahid Faghihi hospital
Full name of responsible person
Nasrin Saki
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Abbas Rezaeian zade
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Nasrin Saki

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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