

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effectiveness of 10% Oxybutynin Topical Gel and 20% Aluminum Chloride in Patients with Primary Hyperhidrosis: a Randomized Double-Blind Controlled Trial

Protocol summary

Study aim

By Comparing the Effectiveness of Topical Oxybutynin Gel 10% and Aluminum Chloride 20% in Patients with Hyperhidrosis, It is Possible to Choose a More Effective Treatment method to Treat this Disease and Help Reduce the Complications Caused by This Disease.

Design

This Study is a Phase 4 Single-Blind Study That Includes 30 Patients. Patients are Individuals with Palmar and Axillary Hyperhidrosis Who Meet the Conditions for Entering the Study

Settings and conduct

A Double-Blind Clinical Trial With 30 Cases of Primary Hyperhidrosis Referred to Afzalipour Hospital, Kerman. Each Side of the Body, Were Randomly Treated with Drug a or b, Once a Day for two Months. At the Beginning and End of the Study, The Iodine-Starch Test, The Hyperhidrosis Severity Scale, Quality of Life Index, Severity of Complications and Rate of Patient Satisfaction Are Evaluated Through a Questionnaire. The Doctor Examining the Effectiveness of the Treatment are Not Aware of the Type of Treatment Performed on Both Sides of The Body

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with Primary Hyperhidrosis of the Palms and Axilla with Intensity 3 and Above and Aged 60-18 Exclusion Criteria: Iontophoresis, Botulinum Toxin Injection, Topical Antiperspirants, Sympathectomy In the Last 6 Months, Pregnant and Lactating Women, Secondary Hyperhidrosis, Sjogren or Sikka Syndrome, Allergy to Aluminum Salts

Intervention groups

This is a Split Study. One Side of The Patient's Body Is Treated with the First Drug and the Other Side is Treated with the Second Drug. One Container of Drug Contains the Topical Gel Contains 10% Oxybutynin and the Other One Contains 20% Aluminum Chloride

Main outcome variables

Severity of the disease, HDSS and DLQI Rating, Site of Involvement and Complications of the Disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221110056463N2**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **retrospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Najmeh Ahramianpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 370 3643

Email address

n.ahramianpour@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of 10% Oxybutynin Topical Gel and 20% Aluminum Chloride in Patients with Primary Hyperhidrosis: a Randomized Double-Blind Controlled Trial

Public title

Comparison of the Effectiveness of 10% Oxybutynin Topical Gel and 20% Aluminum Chloride in Patients with Primary Hyperhidrosis: a Randomized Double-Blind Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primary Excessive Sweating with a Score of 3 or Higher on the Hyperhidrosis Disease Severity Scale (HDSS), at Least in the last 6 Months No Treatment during 6 Months before Entering the Study with Iontophoresis, Botulinum Toxin Injection no Performance of Sympathectomy

Exclusion criteria:

Pregnant and Lactating Women People who have Secondary Excessive Sweating due to an External Factor People with Active Skin Disease such as: Psoriasis, Eczema, Seborrhea and Skin Infection, Glaucoma, Urinary Retention, Myasthenia Gravis, Sjögren's Syndrome or Sicca Syndrome History of Allergy to Aluminum Salts

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The Study is Single-Blind. In this Way: The Person Evaluating the Outcome Does Not Have any Information About the Content of the Drug Used in Each Side and only Checks the Effectiveness of Each Side and Compares it With the Other Side.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Imam Khomeini Highway, Next to Shahid Bahonar University, Afzalipour Hospital, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7171791661

Approval date

2022-11-17, 1401/08/26

Ethics committee reference number

IR.KMU.AH.REC.1400.234

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

Primary Hyperhidrosis

ICD-10 code

R61

ICD-10 code description

Generalized hyperhidrosis

Primary outcomes**1****Description**

Severity of Hyperhidrosis

Timepoint

At the Beginning, Day 30 and 60

Method of measurement

Hyperhidrosis Disease Severity Scale Questionnaire

2**Description**

Dermatology Quality of Life

Timepoint

At the Beginning, Day 30 and 60

Method of measurement

DLQI Questionnaire

3**Description**

Severity of Complications

Timepoint

At the Beginning of the Study and Day 30 and 60
Method of measurement
A self-Made Questionnaire with a Score of 0-2 to Check the Severity of the Complication

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The First Group: A Patient with Hyperhidrosis of the Palm or Axilla, Is Treated with a Topical Gel Containing 10% Oxybutynin on One Side of the Body. It is Explained to the Patient That at Night, 1 cm of the Gel Should Be Applied on the Clean and Dry Skin of the Same Side and It Should Not be Washed For 4 Hours after Use. Use and In the Next 30 Days Reduce It to Once Every Other Night

Category

Treatment - Drugs

2

Description

Intervention group: The second group: a patient with hyperhidrosis of the palm or axilla, is treated with a topical gel containing 20% aluminum chloride on the other side of the body. It is explained to the patient that at night, 1 cm of the gel should be applied on the clean and dry skin of the same side and it should not be washed for 4 hours after use. use and in the next 30 days reduce it to once every other night

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital, Kerman

Full name of responsible person

Najmeh Ahramyanpour

Street address

Imam Khomeini Highway, Next to Shahid Bahonar University, Afzalipour Hospital, Kerman,Iran

City

Kerman

Province

Kerman

Postal code

7171791661

Phone

+98 917 370 3643

Email

n.ahramianpour@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Najmeh Ahramyanpour

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Imam Khomeini Highway, Next to Shahid Bahonar University, Afzalipour Hospital, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7171791661

Phone

+98 34 3132 8237

Email

n.ahramianpour@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Najmeh Ahramyanpour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Imam Khomeini Highway, Next to Shahid Bahonar University, Afzalipour Hospital, Kerman,Iran

City

Kerman

Province

Kerman

Postal code

7171791661

Phone

0098341328237

Email

najmeh.pour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Najmeh Ahramianpour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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City

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Province

Kerman

Postal code

7171791661

Phone

+98 917 370 3643

Fax

Email

n.ahramian@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Najmeh Ahramianpour

Position

Assistant Professor

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Dermatology

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Province

Kerman

Postal code

7171791661

Phone

+98 917 370 3643

Fax

Email

n.ahramian@kmu.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