Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 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

Street address

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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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

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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City
Kerman

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