

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation of iontophoresis with aluminum chloride hexahydrate gel versus iontophoresis with Tap water in people with primary palmar hyperhidrosis

Protocol summary

Study aim

Comparative evaluation of effectiveness and persistence of iontophoresis with aluminum chloride hexahydrate gel versus iontophoresis with Tap water in people with primary palmar hyperhidrosis

Design

Two arm parallel groups randomized trial

Settings and conduct

This study will be done in Shahid Beheshti Rehabilitation clinic. Iontophoresis with ACH gel will applied to the first group (n=16) and Iontophoresis with tap water will used for the second group (n=16). Sweating rate before and after the iontophoresis will measured with gravimetry test and QOL will measured with DLQI, 3days, 1 week, 2 weeks, 3 weeks, 4 weeks, 8 weeks and 6 months after the treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria : age 18-40, BMI 17-30, the presence of focal, visible sweating for at least 6 months without any obvious cause, besides the presence of at least two of the following characteristics: Bilateral and relatively symmetrical sweating, frequency of at least one episode per week, impairment of daily activities of the patient, age of onset less than 25 years, a positive family history and cessation of focal sweating during sleep. Having HDSS grade 2 or 3. Exclusion criteria : having pacemaker or substantial metal implants located in electrical current path, being pregnant, suffering from systemic disease leading to hyperhidrosis and any central or peripheral nervous system diseases. SSR (sympathetic skin response) greater than normal or absent SSR

Intervention groups

The first group (n=16) will receive iontophoresis with ACH gel. For the second group (n=16), iontophoresis will perform with tap water. Iontophoresis will applied to the patient's dominant (right) hand. An iontophoresis stimulator (ActivaDose, iontophoresis delivery unit, Serial

Number 12080971) with an intensity of 2 mA for 30 min will be used

Main outcome variables

1.sweating rate.2. DLQI questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160506027762N2**

Registration date: **2020-02-09, 1398/11/20**

Registration timing: **retrospective**

Last update: **2020-02-09, 1398/11/20**

Update count: **0**

Registration date

2020-02-09, 1398/11/20

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77263613

Email address

eghandali@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of iontophoresis with aluminum chloride hexahydrate gel versus iontophoresis with Tap water in people with primary palmar hyperhidrosis

Public title

Effect of aluminum chloride hexahydrate gel iontophoresis on hyperhidrosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-40, BMI 17-30. presence of focal, visible sweating for at least 6 months without any obvious cause, besides the presence of at least two of the following characteristics: Bilateral and relatively symmetrical sweating, frequency of at least one episode per week, impairment of daily activities of the patient, age of onset less than 25 years, a positive family history and cessation of focal sweating during sleep. HDSS 2 or 3 .

Exclusion criteria:

Having pacemaker or substantial metal implants located in electrical current path, being pregnant, suffering from systemic disease leading to hyperhidrosis and any central or peripheral nervous system diseases. SSR (sympathetic skin response) greater than normal or absent SSR

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **32****Randomization (investigator's opinion)**

N/A

Randomization description**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**

Shahid Beheshti University of medical Sciences

Street address

Building number2, Shahid Beheshti University of Medical Sciences, Velenjack, next to Teleghani Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-01-07, 1396/10/17

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.833

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

Palmar hyperhidrosis

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

Sweating rate

Timepoint

before and 3 days, 1, 2, 3, 4, 8 weeks, and 24 weeks after the last treatment session

Method of measurement

Sweating rate with gravimetry test

2**Description**

Quality of Life score in DLQI questionnaire

Timepoint

before and 3 days, 1, 2, 3, 4, 8 weeks, and 24 weeks after the last treatment session

Method of measurement

Quality of Life score with DLQI questionnaire

Secondary outcomes**1****Description**

Sympathetic Skin Response (SSR)

Timepoint

Before and after the application of one session iontophoresis

Method of measurement

Using a Medelec Synergy Electromyography instrument

Intervention groups

1

Description

Intervention group: 16 patients with Palmar hyperhidrosis will receive iontophoresis with aluminum chloride hexahydrate gel (manufactured in department of pharmaceutical of Shahid Beheshti University of Medical Sciences)

Category

Rehabilitation

2

Description

Intervention group: 16 patients with Palmar hyperhidrosis will receive iontophoresis with tap water

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic Shahid Beheshti Rehabilitation School

Full name of responsible person

Seyed Majid Hosseini

Street address

School of Rehabilitation, Opposite to Bou Ali Hospital, Damavand Road, Tehran

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1723

Email

majidhosseini44@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Building number2, Shahid Beheshti University of Medical Sciences, Velenjack, next to Teleghani Hospital

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Postal code

1985717443

Phone

+98 21 8820 0096

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

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

School of Rehabilitation, Shahid Beheshti University of medical Sciences

Full name of responsible person

Seyed Majid Hosseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic information and variables are shared

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To continue research and get acquainted with the method of work and It is only available to researchers working in academic and scientific institutions

From where data/document is obtainable

Seyed Majid Hosseini majidhosseini44@yahoo.com

What processes are involved for a request to access data/document

After the request is received by email as soon as the data reaches him

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

School of Rehabilitation, Shahid Beheshti University of
medical Sciences

Full name of responsible person

Seyed Majid Hosseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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