

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison the effect of long-pulsed ND-YAG laser and aluminum chloride 20% in the treatment on axillary hyperhidrosis

Protocol summary

Study aim

Comparison the effect of long-pulsed ND-YAG laser and aluminum chloride 20% in the treatment of axillary hyperhidrosis

Design

Two arm parallel group randomised non-blinded clinical trial. Randomisation was done using flip a coin method. In case of head, patients will be treated by laser and in case of tails, aluminum chloride will be given as treatment.

Settings and conduct

Fifteen (15) patients with axillary hyperhidrosis which have inclusion criteria and attending to Shohadaye-Tajrish Hospital will be selected. Intervention group 1 will be treated with long pulsed ND-Yag with hair removal setting each month for 3 consecutive months. Intervention group 2 will be treated with aluminum chloride 20 % applying daily for 3 months. At the end of 3 months and 6 months after treatment area of hyperhidrosis will be indicated with iodine starch test and compared between 2 groups. In addition, treatment results will be assessed using global physician scale by comparing digital photos taken a tbaseline and at the end of the treatment. Scaling would be as: mild improvement (decrease in sweating by 0-25%); Moderate improvement: (decrease in sweating by 25-50%); Good improvement: (decrease in sweating by 50-70%); Excellent improvement: (decrease in sweating by 75-100%).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age older than 18 years; having axillary hyperhidrosis; hyperhidrosis lasting for 6 months or more. Non-inclusion criteria: using drugs which affect sweating such as anticholinergic; adenergic, antipsychotic ect; secondary cause of sweating such as infection; neurological disease, neoplasm

Intervention groups

Intervention group 1: individuals are treated with Aluminum chloride 20% daily for 3 months Intervention

group 2: individuals are treated with ND-Yag-laser with hair removal setting (frequency of 1 Hz, pulse of 30ms and energy of 30 J/Cm²) each month for 3 consecutive months

Main outcome variables

axillary sweating

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190212042683N2**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

Tara Barat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2211 8152

Email address

barat_t@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of long-pulsed ND-YAG laser and aluminum chloride 20% in the treatment on axillary hyperhidrosis

Public title

The effect of long-pulsed ND-YAG laser on the treatment of axillary hyperhidrosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 18 years old Having hyperhidrosis defined as sweating which stain axillary region more than 5 cm using Iodine starch test hyperhidrosis lasting for 6 month or more

Exclusion criteria:

Using drugs which affect sweating such as anticholinergic, adernergic and antipshychotic drugs second cause of sweating such as infection, neurological disease and malignancy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using flip the coin method

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 Beheshti University of Medical Sciences,
Yaman street, Shahid Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2018-12-09, 1397/09/18

Ethics committee reference number

IR.SBMU.SRC.REC.1397.018

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

axillary hyperhidrosis

ICD-10 code

R61.0

ICD-10 code description

Localized hyperhidrosis

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

Axillary sweating amount

Timepoint

base line, after treatment (month 3) and 6 months after treatment

Method of measurement

Iodine starch test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Participants will be treated with Long pulsed ND-YAG laser with hair removal setting once a month

Category

Treatment - Devices

2**Description**

Intervention group 2: Patients will be treated with aluminum chloride 20% daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Mehdi gheisari

Street address

Shohadaye Tajrish Hospital, Shahr-dari St, Tajrish Square, Tehran town

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Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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

Tara Barat

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Position

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1981959311

Phone

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Email

Dr_t_barat@yahoo.com

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

General information of participants such as age, sex and family history

When the data will become available and for how long

Six months after publication of article

To whom data/document is available

Researchers in academic institution

Under which criteria data/document could be used

For research purpose after sending an official request to skin research center of Shahid Beheshti University of Medical Sciences

From where data/document is obtainable

Mehdi Gheisari; sending Email to src@sbmu.ac.ir or call the telephone number 00982122741507

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

Sending an official request to skin research center of Shahid Beheshti University of Medical Sciences

Comments