Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 hyperhydrosis 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; adernergic, antipshychotic 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

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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, Shahrdari St, Tajrish Square, Tehran town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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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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