

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of the effect of Fractionated Microneedle Radiofrequency in the treatment of severe primary axillary hyperhidrosis

Protocol summary

Summary

Primary Axillary Hyperhidrosis is excessive sweating in the area of the axilla. There are several different treatment options for Primary Axillary Hyperhidrosis. Recently, Fractionated Microneedle Radiofrequency devices have been shown to be effective for the treatment of primary axillary hyperhidrosis. The aim of this study was to evaluate the clinical effectiveness and safety of Fractionated Microneedle Radiofrequency for the treatment Primary Axillary Hyperhidrosis. Design: single-blind, sham-control right-left comparative clinical trial. Participants including criteria: 1) Having the complaint of Primary axillary hyperhidrosis and score 3 or 4 in Hyperhidrosis Disease Severity Scale (HDSS). 2) Age between 18-50 years 3) both genders. Setting and conduct: 25 participants with Primary axillary hyperhidrosis selected and he/she underwent FMR (INFINI TM; Lutronic, Goyang, Korea®) 3 sessions, at 3-week intervals on the left axilla. In right axilla (sham-control) the device was on standby mode. Clinical improvement evaluated using the Hyperhidrosis Disease Severity Scale (HDSS), starch-iodine test, Sweating intensity visual analog scale (VAS). Patients Satisfaction was obtained using the Dermatology Life Quality Index (DLQI) and a 6-point scale. Adverse reactions of the treatments were recorded at every follow-up visit. Main outcome measured at 1 and 3 weeks after each session and 3 months after the last session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111915455N1**

Registration date: **2014-01-23, 1392/11/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-23, 1392/11/03

Registrant information

Name

Bahareh Abtahi-Naeini

Name of organization / entity

Skin Diseases and leishmaniasis research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of research of Isfahan University of Medical Sciences .

Expected recruitment start date

2013-10-31, 1392/08/09

Expected recruitment end date

2013-11-30, 1392/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of Fractionated Microneedle Radiofrequency in the treatment of severe primary axillary hyperhidrosis

Public title

Treatment of axillary hyperhidrosis by Microneedle Radiofrequency.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having the complaint Primary Axillary Hyperhidrosis and score 3 or 4 in Hyperhidrosis Disease Severity Scale (HDSS); Age between 18-50 years ; both genders ; Willingness for participation in the study and signing the consent form Exclusion criteria: Pregnant or breast-feeding women ; active infection at the axilla ; taking anticholinergic drug ; heart pace-maker or cardiac defibrillator ; taken botulinum toxin injections in the axillae within the previous 6 months ; Patients who have propensity for keloid formation

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sham-control right-left comparative clinical trial. Right axilla as a sham control

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences.

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

City

Isfahan

Postal code

Approval date

2013-10-30, 1392/08/08

Ethics committee reference number

392507

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

Severity of sweating

Timepoint

1 and 3 weeks after each session and 3 months after the last session.

Method of measurement

Hyperhidrosis Disease Severity Scale (HDSS) - Sweating intensity visual analog scale (VAS)

2

Description

Patients satisfaction

Timepoint

At base line - at the end of the study.

Method of measurement

6-point scale

Secondary outcomes

1

Description

Edema

Timepoint

1 and 3 weeks after each session and 3 months after the last session.

Method of measurement

Examination

2

Description

Quality of life

Timepoint

At base line - at the end of the study

Method of measurement

Dermatology Life Quality Index (DLQI)

3

Description

Pigmentation

Timepoint

1 and 3 weeks after each session and 3 months after the last session.

Method of measurement

Examination

4

Description

Compensatory hyperhidrosis

Timepoint

1 and 3 weeks after each session and 3 months after the last session.

Method of measurement

Ask the subjects

5

Description

Local reactions

Timepoint

1 and 3 weeks after each session and 3 months after the last session.

Method of measurement

Examination

Intervention groups

1

Description

The left axilla was treated with a total of 3 passes of Fractionated Microneedle Radiofrequency. The treatment parameters included : The depth was at 2-3 mm; The energy level was at 6- 10 Jules; The Time was at 120-180 m sec with a small range ($\pm 10\%$) of variation for energy and time.

Category

Treatment - Other

2

Description

The right axilla was treated with a total of 3 passes of Fractionated Microneedle Radiofrequency when the device was on standby mode (sham control).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

AL-Zahra hospital

Full name of responsible person

Dr bahareh Abtahi-Naeini

Street address

Department of Dermatology, Al-Zahra hospital, Isfahan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Ebrahim Esfandiari

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

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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

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin disease and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Ira

Full name of responsible person

Dr bahareh Abtahi-Naeini

Position

Assistant of Dermatology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty