Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 (±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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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