Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical effect of percutaneous ethanol injection in the treatment of osmidrosis

Protocol summary

Summary

Osmidrosis is perspiration odor in the area of the axilla. There are several different treatment options for osmidrosis. Recently, percutaneous ethanol injection has been shown to be effective for the treatment of osmidrosis. The aim of this study was to evaluate the clinical effectiveness and safety of percutaneous ethanol injection for the treatment osmidrosis. Design: single-blind, case-control comparative clinical trial between Percutaneous Ethanol Injection's efficacy with percutaneous injection of saline as placebo. Participants including criteria: 1) Having the complaint of osmidrosis. 2) Age between 12-35 years old. 3) Both genders. Setting and conduct: 60 patients with osmidrosis selected, case group with 30 patients and control group with 30 patients. In case group after local anesthesia, 90% ethanol was injected into the subcutaneous layer (near the interface of the dermis, where the sweat glands are located) using a 2.5 mL syringe with a 30 G needle, it was easily visible underneath the skin. The average amount of ethanol injected per side was 8.9 mL. In control group after local anesthesia, saline was injected into the subcutaneous layer near the interface of the dermis. Clinical improvement evaluated using the osmidrosis, starch-iodine test, visual analog scale (VAS). Biopsy will be examined from a patient before and after treatment. Adverse reactions of the treatments were recorded at every follow-up visit. Main outcome measured at 10 months after the procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122420426N1**
Registration date: **2015-04-09, 1394/01/20**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-04-09, 1394/01/20

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical effect of percutaneous ethanol injection in the treatment of osmidrosis

Public title

Osmidrosis treatment with percutaneous ethanol injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having the complaint osmidrosis; age between 12-35 years old; 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.

Age

From **12 years** old to **35 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar Jarib Avenue , Isfahan

City

Isfahan

Postal code

Approval date

2013-04-16, 1392/01/27

Ethics committee reference number

393205

Health conditions studied

1

Description of health condition studied

Osmidrosis

ICD-10 code

L75

ICD-10 code description

Apocrine sweat disorders

Primary outcomes

1

Description

osmidrosis

Timepoint

after ten months of injection

Method of measurement

starch-iodine test , visual analog scale(VAS)

Secondary outcomes

1

Description

Patients satisfaction

Timepoint

At base line – at the end of the study

Method of measurement

visual analog scale (VAS)

Intervention groups

1

Description

30 Patients ranged in age from 12 to 35 years in case group were treated with percutaneous ethanol injection well. The injection procedure was carried out in an outpatient basis. Patients were placed in a supine position with their arms abducted about 100 degrees to expose the axilla. Marks were made around the location of the axillary hair-bearing area, where the apocrine glands are located. When we first started using the technique, grid-pattern markings were used to reduce the chances of uneven distribution of the ethanol.

Category

Treatment - Other

2

Description

30 Patients ranged in age from 12 to 35 year in control group as placebo were treated with percutaneous saline injection well. The injection procedure was carried out in an outpatientbasis. Patients were placed in a supine positionwith their arms abducted about 100 degrees toexpose the axilla. Marks were made around thelocation of the axillary hair-bearing area, where the apocrine glands are located. When we first startedusing the technique, grid-pattern markings were usedto reduce the chances of uneven distribution of thesaline.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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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
Vice Chancellor foer research of 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

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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