

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of effect of Transcutaneous Electrical Nerve Stimulation (TENS) and lidocaine spray on pain intensity during insertion of vascular needles in hemodialysis patients

Protocol summary

Summary

Introduction: Pain is one of the most problematic in human experiences that is peak of physical and psychological problems. Experience of pain during needle insertion is unavoidable in hemodialysis settings and patients explain it as a worst experience during hemodialysis. It is important to find interventions for pain relief during the needle insertion in hemodialysis patients. Aim: The comparison of effect of Transcutaneous Electrical Nerve Stimulation (TENS) and lidocaine spray on pain intensity during insertion of vascular needles in hemodialysis patients. Method: Thirty hemodialysis patients of hemodialysis ward who are eligible are selected. Four interventions including TENS, Placebo-TENS, Lidocaine spray, Lidocaine placebo spray are performed for any patient in sequential sessions of hemodialysis with randomly assignment before the arterial needle insertion. The severity of pain during arterial needle insertion is measured by "Numeric Pain Intensity Scale". The Friedman test is used for evaluation of difference among means the severity of pain in four different conditions.

General information

Acronym

TENS

IRCT registration information

IRCT registration number: **IRCT201008254548N1**

Registration date: **2010-11-13, 1389/08/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-11-13, 1389/08/22

Registrant information

Name

Nahid Hoshmand motlagh

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effect of Transcutaneous Electrical Nerve Stimulation (TENS) and lidocaine spray on pain intensity during insertion of vascular needles in hemodialysis patients

Public title

The effect of Transcutaneous Electrical Nerve Stimulation (TENS) and lidocaine spray on pain intensity during insertion of vascular needles in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: (1) The patient be alert, (2) The patient does not intake analgesic and narcotic drugs before 6 hours, (3) Not to have any pain in other parts of body, (4) Not to have internal cardiac pacemaker, (5) The patient must have arterio-venous fistula for venous access.

Exclusion criteria: (1) To attend the study is completely optional, So the patient can avoid from study whenever he/she want, without any change in personnel's behavior or care, (2) At the first action, if the patient 's vessels are not achievable , he/she is omitted from study, (3) patients who are in the low consciousness and cognition condition and could not answer the questions, (4) If the patient is transferred to other centers during studying.

Age

From **10 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Nursing and Paramedicine Faculty, Semnan University
Of Medical Sciences

City

Semnan

Postal code

35131038111

Approval date

2010-08-24, 1389/06/02

Ethics committee reference number

5513/1/3

Health conditions studied

1

Description of health condition studied

chronic renal failure

ICD-10 code

N180

ICD-10 code description

End-stage renal disease

Primary outcomes

1

Description

Intensity pain

Timepoint

One minute after entering the arterial needle

Method of measurement

Numeric Pain Intensity Scale

Secondary outcomes

empty

Intervention groups

1

Description

Fourth intervention (TENS placebo): TENS is turned off and researcher place TENS electrodes with 6 centimeter distance from each other on the skin near the location of insertion of arterial needle. One minute after to place TENS electrodes on the skin, whereas TENS is turn off so, hemodialysis needle (gauge 16) is inserted into vascular in fistula area by dialysis ward nurse. One minute later, the pain severity is measured with Numeric Pain Intensity Scale by nurse.

Category

Placebo

2

Description

First intervention (TENS): TENS electrodes are placed on the skin with 6 centimeter distance from each other near the location of insertion of arterial needle by researcher. Then the TENS is turned on with frequency 100 Hz and pulse duration 0/1msec by researcher. One minute after using TENS, hemodialysis needle (gauge 16) is inserted into vascular in fistula area by dialysis ward nurse. One minute later, the pain severity is measured with Numeric Pain Intensity Scale by nurse.

Category

Treatment - Devices

3

Description

Second intervention (lidocaine placebo spray): Lidocaine placebo spray is water that is filled in emptied lidocaine spray bottle. 2 puffs are used from distance 5 centimeter on the skin in location of needle insertion by researcher.

5 minutes later, hemodialysis needle (gauge 16) is inserted by dialysis ward nurse.

Category

Placebo

4

Description

Third intervention (lidocaine spray): 2 puffs of lidocaine 10% spray (each puff include 10mg lidocaine) are used from distance 5 centimeter on the skin in location of insertion of arterial needle by researcher. 5 minute later, hemodialysis needle (gauge 16) is inserted by dialysis ward nurse. One minute later, the pain severity is measured with Numeric Pain Intensity Scale by nurse.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital

Full name of responsible person

Nahid Hoshmand Motlagh

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Hefdah Shahrivar Blvd

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Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Raheb Ghorbani (Ph.D)

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Semnan University of Medical Sciences and Health Services, Basij Blvd

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Semnan

Grant name

اعتبارات پژوهشی دانشگاه علوم پزشکی

Grant code / Reference number

441

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Semnan University Of Medical Sciences

Full name of responsible person

Nahid Hoshmand Motlagh

Position

Postgraduate student

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