# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 hemodiaysis ward who are eligible are selected. Four interventions including TENS, Placebo-TENS, Lidocain spray, Lidocain 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)

**Phone**

+98 23 3105 2114

**Email address**

hoshmand@sem-ums.ac.ir

**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 veonous 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 (gaoge 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 (gaoge 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 (gaoge 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 (gaoge 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

**Street address**

Hefdah Shahrivar Blvd

**City**

Semnan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Raheb Ghorbani (Ph.D)

**Street address**

Semnan University of Medical Sciences and Health Services, Basij Blvd

**City**

Semnan

**Grant name**

اعتبارات پژوهشي دانشگاه علوم پزشكي

**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**

**Street address**

Nursing and Paramedicine Faculty, Semnan University Of Medical Sciences

**City**

Semnan

**Postal code**

35131038111

**Phone**

+98 32 1335 4191

**Fax**

+98 23 1335 4190

**Email**

Hoshmand@sem-ums.ac.ir

**Web page address**

www.sem-ums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Semnan University Of Medical Sciences

**Full name of responsible person**

Mohammad Reza Asgari

**Position**

PhD

**Other areas of specialty/work**

**Street address**

Nursing and Paramedicine Faculty, Semnan University Of Medical Sciences

**City**

Semnan

**Postal code**

35131038111

**Phone**

+98 23 1335 4191

**Fax**

+98 23 1335 4190

**Email**

Asgari@Sem-Ums.ac.ir

**Web page address**

www.sem-ums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Semnan Universiyt OF Medical Sciences
**Full name of responsible person**
Nahid Hoshmand Motlagh
**Position**
Postgraduate student
**Other areas of specialty/work**
**Street address**
Nursing and paramedicine Faculty, Semnan university Of Medical sciences
**City**
Semnan
**Postal code**
35131038111
**Phone**
+98 23 1335 4191
**Fax**
+98 23 1334 5190
**Email**
hoshmand@sem-ums.ac.ir
**Web page address**
www.sem-ums.ac.ir

## 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*