

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparative study of transcutaneous electrical nerve stimulation (TENS) and acupressure on chemotherapy-induced nausea and vomiting.

#### Protocol summary

##### Study aim

The purpose of this randomized clinical trial is to compare the effects of electrical stimulation (TENS) and acupressure on nausea and vomiting induced by chemotherapy.

##### Design

In this research, 120 eligible patients undergoing chemotherapy will be randomly recruited into one of 4 groups: intervention 1 and 2, and controls 1 and 2. The method of randomization is based on the sealed envelope. All patients are unaware of the exposure. In this study, the patient is identified with a code in the envelope, and it is determined elsewhere that this is an intervention number or a placebo. The phase of the clinical trial is not applicable in this study.

##### Settings and conduct

The purpose of this randomized clinical trial is to compare the effects of electrical stimulation of skin (TENS) and acupressure on nausea and vomiting induced by chemotherapy.

##### Participants/Inclusion and exclusion criteria

The study population is all cancer patients over 18 years of age who are referred to Cancer Research Department of Kowsar Hospital. The main inclusion criteria are the history of receiving at least one chemotherapy course and a history of nausea experience following previous chemotherapy sessions. The main exclusion criteria are receiving radiotherapy (total or upper abdominal) simultaneously with chemotherapy and the use of drugs or other therapies to reduce nausea.

##### Intervention groups

Intervention group 1: receiving TENS electric stimulation for 30 minutes at 10 Hz and a 500 msec pulse duration, with a tolerable intensity, to the P6 point of the wrist, once daily, on both hands for 5 consecutive days. Intervention group 2: Acupuncture wrist band on the P6 point of the wrist, permanently, on both hands for 5 consecutive days. Control group 1: receiving placebo TENS electric stimulation for 30 minutes to the P6 point

of the wrist, once daily, on both hands for 5 consecutive days. Control group 2: ordinary wrist band on the P6 point of the wrist, permanently, on both hands for 5 consecutive days.

##### Main outcome variables

nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100618004203N14**

Registration date: **2018-01-02, 1396/10/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-02, 1396/10/12**

Update count: **0**

##### Registration date

2018-01-02, 1396/10/12

##### Registrant information

##### Name

Atefeh Aminian Far

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 1335 4180

##### Email address

aminianfar@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for research, Semnan University of Medical Sciences

##### Expected recruitment start date

2017-12-21, 1396/09/30  
**Expected recruitment end date**  
2018-05-05, 1397/02/15  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparative study of transcutaneous electrical nerve stimulation (TENS) and acupuncture on chemotherapy-induced nausea and vomiting.

**Public title**  
Transcutaneous electrical nerve stimulation (TENS), acupuncture and chemotherapy-induced nausea and vomiting.

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age over 18 Use of nauseous diets such as cisplatin alone or in combination with other chemotherapeutic agents with the same amount and administration in two cycles of chemotherapy without planning for radiotherapy in cycles At least four times chemotherapy  
**Exclusion criteria:**  
Having a history of nausea and vomiting for reasons other than chemotherapy;; Taking anti-epithelial (emend) medication Treatment with corticosteroid medications during the cycles Using pacemakers

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization tool: Sealed envelope

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Patients do not understand which of the two control or test groups belong. All patients are unaware of the exposure. In this study, the patient is identified with a code in the envelope, and it is determined elsewhere that this is an intervention number or a placebo.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

##### Street address

Bassij Blvd, Semnan University of Medical Sciences, Semnan, Iran.

##### City

Semnan

##### Province

Semnan

##### Postal code

3519899951

#### Approval date

2017-10-19, 1396/07/27

#### Ethics committee reference number

ir.semums.rec.1396.110

## Health conditions studied

### 1

#### Description of health condition studied

Cancer

#### ICD-10 code

C00-C75

#### ICD-10 code description

Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue

## Primary outcomes

### 1

#### Description

nausea and vomiting

#### Timepoint

In hours 1,2,3 and 4 after intervention and 24 hours after beginning of chemotherapy and 5 days later.

#### Method of measurement

checklist and cortilla tool

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the intervention group 1: receiving TENS electric stimulation for 30 minutes at 10 Hz and a 500 msec

pulse duration, with a tolerable intensity, to the P6 point of the wrist, once daily, on both hands for 5 consecutive days.

**Category**

Prevention

**2****Description**

In the intervention group 2: Acupuncture wrist band on the P6 point of the wrist, permanently, on both hands for 5 consecutive days.

**Category**

Prevention

**3****Description**

In the control group 1: receiving placebo TENS electric stimulation for 30 minutes to the P6 point of the wrist, once daily, on both hands for 5 consecutive days.

**Category**

Prevention

**4****Description**

In the control group 2: ordinary wrist band on the P6 point of the wrist, permanently, on both hands for 5 consecutive days.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kosar hospital of Semnan

**Full name of responsible person**

Dr Atefeh Aminian Far

**Street address**

Basij Blvd

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atf.amin@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr, Ali Rashidipour

**Street address**

Bassij Blvd, Deputy of Research, Semnan University of Medical Sciences, Semnan, Iran

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aminfar83@yahoo.com

**Grant name****Grant code / Reference number****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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Atefeh Aminian Far

**Position**

Ph.D of Physiotherapy/ Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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aminfar@semums.ac.ir

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Atefeh Aminian Far

**Position**

Ph.D of Physiotherapy/ Assistant Professor

**Latest degree**

Ph.D.

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

## Person responsible for updating data

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Atefeh Aminian Far

**Position**