Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 23 1335 4180

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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 acupressure on chemotherapy-induced nausea and vomiting.

Public title

Tanscutaneous electrical nerve stimulation (TENS), acupressure 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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3519899951

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Person responsible for updating data

Contact

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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