

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of ice massage on nausea and vomiting of cancer patients under chemotherapy in the selective hospitals of Tehran

Protocol summary

Summary

Purposes: prevention and control of nausea and vomiting is an important intervention in cancer patients. This study was performed with the aim of assessing the impact of ice massage on pericardium point (P6 or neiguan) by using ice mold on nausea and vomiting of cancer patients under chemotherapy. Methods and Materials: In a single blind randomized control clinical trial, 114 patients were studied by random allocation method in three groups of test, placebo and control. In the case group, the neiguan point of wrist was massaged slowly and gently by using the ice mold in the wet gauze that was placed by the patient or his accompany for 7 minutes twice a day with 12 hours interval. The placebo group was massaged in a same pattern by using wooden cube and the control group did not receive any action. Nausea and vomiting state were evaluated in three groups of samples by using the Morrow Assessment of Nausea and Emesis (MANE) questionnaire in 4 periods of time in 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804222046N1**

Registration date: **2009-07-13, 1388/04/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2009-07-13, 1388/04/22

Registrant information

Name

Mehdi Sadeghi Shermeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

MSc Nursing student thesis

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2009-10-22, 1388/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ice massage on nausea and vomiting of cancer patients under chemotherapy in the selective hospitals of Tehran

Public title

Effect of ice massage on nausea and vomiting of cancer patients under chemotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Chemotherapy drug regimens containing only Cisplatin and Etoposide received for the first time. 2. Using only Kytril for control of nausea and vomiting. 3. Lack of distraction and symptoms of psychotic history such as hallucinations and severe depression. 4. Absence of severe cardiac dysrhythmia. 5.

Lack of uncontrolled hypertension. 6. Lack of respiratory discomforts. 7. Absence of brain metastasis and upper digestive system cancer and known metastasis. 8. Absence of electrolyte disorders 9. No consumption of drugs that cause drowsiness and disorientation. 10. Lack of musculoskeletal problems such as arthritis. 11. Lack of vascular problem in the neiguan point (with Allen test). 12. Only use chemotherapy method for cancer. 13. Absence of gastrointestinal or metabolic disease that will create nausea and vomiting (intestinal obstruction, gastritis, inflammation of oral mucosa, increased blood calcium, decreased blood sodium and uremia). 14. At least one of the patient's hands have no injury (ulcer or amputation) that prevent the implementation of ice massage or touch massage. 15. having more than 12 years old. 16. No visual impairment that prevents to see visual criteria of nausea severity measure. 17. The patient himself or his accompany is literate for filling the daily status report form. 18. BMI between 20 to 30. Exclusion criteria: 1. changing chemotherapy regime during the research. 2. Severe complications after chemotherapy and need to have care in the intensive care unit.

Age

From **12 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **114**

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**

Baqiyatallah University of Medical Sciences

Street address

Mollah Sadra

City

Tehran

Postal code

1956837173

Approval date

2009-07-13, 1388/04/22

Ethics committee reference number

347

Health conditions studied**1****Description of health condition studied**

Chemotherapy

ICD-10 code

Z51.1

ICD-10 code description

Chemotherapy session for neoplasm

2**Description of health condition studied**

Cancer

ICD-10 code

C80

ICD-10 code description

Malignant neoplasm without specification of site

Primary outcomes**1****Description**

Decrease of nausea and vomiting due to Chemotherapy

Timepoint

Every one hour

Method of measurement

Morrow Assessment of Nausea and Emesis (MANE)
Questionnaire

Secondary outcomes**1****Description**

Decrease of Anti emetic drugs usage

Timepoint

24 hours

Method of measurement

By Checklist

Intervention groups**1****Description**

Ice massage on pericardium 6 in case group

Category

Other

2**Description**

Massage with wooden cube in Placebo group

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Imam Khomeini Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Abbas Ebadi
Street address
Aghdasieh
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Baqiyatallah 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

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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