

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment the of massage therapy and music on nausea and vomiting caused by chemotherapy in children with cancer admitted to oncology ward

Protocol summary

Summary

Introduction: Nausea and vomiting are chemotherapy side effects and some medical and non medical treatments are used for their control. The aim of this study is to assess the effectiveness of massage and music therapy on post chemotherapy nausea and vomiting in cancer children in pediatrics oncology ward. Method: This is a clinical trial study with crossover design. In a convenience manner both groups achieve one intervention alternatively. Severity of nausea and vomiting before, immediate and 1 hour after chemotherapy will be measured by Visual Analog Scale and BARF and in 12 hours with Rhodes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120819862N4**
Registration date: **2017-08-11, 1396/05/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-11, 1396/05/20

Registrant information

Name

Sakine Sabzevari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the of massage therapy and music on nausea and vomiting caused by chemotherapy in children with cancer admitted to oncology ward

Public title

Massage therapy and music on nausea and vomiting caused by chemotherapy in children with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Children with neoplasm diagnosis and 7-15 years old; Has chemotherapy order; Achieve at least one dose of chemotherapy and experienced nausea and vomiting. Exclusion criteria: Some side effects such as infection; Bleeding; Sepsis; DIC; Referred to other clinical centers; Death belong the time of this research.

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features

In first time children are divided two groups: Massage and music therapy then achieved one intervention, data are recorded for 24 hours. Then any intervention is done for each groups. In first step massage group listen music and music group massage. At this stage, 24-hour findings of nausea and vomiting will be recorded.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences

Street address

Vice chancellor for research, Tahmasb abad four way

City

Kerman

Postal code

76177

Approval date

2016-09-23, 1395/07/02

Ethics committee reference number

Ir.Kmu.REC.1395.545

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

Neplasm

ICD-10 code

C00-C97

ICD-10 code description

نئوپلاسم بدخيم

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

Nausea and vomiting

Timepoint

Before and after intervention

Method of measurement

Adapted Rhodes Index of Nausea and Vomiting for Child, VAS

2**Description**

Nausea and vomiting

Timepoint

Before and after intervention

Method of measurement

Visual Analog Scale and Adopted Rhodes index Of Nausea and vomiting

Secondary outcomes

empty

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

In the first stage, children are divided into two groups, massage and music, that each group achieves one intervention. Data records for 24 hours. Then, in order to eliminate the effect of intervention in the next session, no intervention is required (period of clearing). In the second phase, the group who received the first massage will receive a music session at the same time, and. At this stage, 24-hour findings of nausea and vomiting will be recorded. The massage used in this study is Swedish massage, which includes rubbing movements, soft, long and light stroke, rhythmic stroke, and impulse in superficial muscle layers. Relaxation massage is also combined with joints movements by stretching the muscles, they can relieve pain. Swedish massage includes two sections of energy and relaxation. The four general moves of Swedish massage are as follows: 1- Nosebleed: Soft and quiet movement for relaxation of the soft texture of the rubbing: pressing and rolling that follows the movements of the stomach 2- 3- Friction: deep and circular movements that cause the layer. The tissues are rubbed together, which ultimately leads to increased blood pressure and loss of tissue injuries. 4- Short and short strokes with hands in the shape of the cup, also using the fingers and edges of the hands for massage 20 minutes and half an hour before the chemotherapy. Music that will be used in this study will include a list of all types of music ready and recorded, and after consultation with the parents of the desired music of the child, selected by the researcher using hearing aids from the headphones and walkman. It starts at about 15 minutes before and in length chemotherapy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital Ahwaz

Full name of responsible person

Sakineh Akbari

Street address

City

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Campus of Medical University, Haftbagh Highway

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University Of Medical Sciences

Full name of responsible person

Vice Chancellor of Research

Street address

Vice chancellor of Research, Tahmasb abad
Crossroads

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr Sakineh Sabzevari

Position

Phd of Nursng education/Assisstant professor

Other areas of specialty/work

Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Sakineh Sabzevari

Position

Phd of Nursing Education/assistant professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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