Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 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

+98 34 3132 5219

Email address

s_sabzevari@kmu.ac.ir

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 reserch, 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 بدخیم

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
Śhafa Hospital Ahwaz
Full name of responsible person
Sakineh Akbari
Street address
City
Ahwaz

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
Campus of Medical University, Haftbagh Highway
City
Kerman
Postal code
76177
Phone
+98 34 3132 5219
Fax
Email
S_Sabzevari@kmu.ac.ir; sabzevariz@yahoo.com
Web page 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
Street address
Campus of medical University, Haft Bagh Highway
City
Kerman
Postal code
76177
Phone
+98 34 3132 5219
Fax
Email
S_Sabzevari@kmu.ac.ir; sabzevariz@yahoo.com
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