

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of effleurage massage with clove oil on IT/LP pain and anxiety among children with cancer: A randomized clinical trial.

Protocol summary

Study aim

Determining the effect of effleurage massage with clove oil on pain and anxiety in children with cancer undergoing Lumbar puncture/intra spinal injection(IT/LP)

Design

The clinical trial has control group, with parallel groups and one-sided blind , randomized using by the random sample numbers software, phase 3 on 39 sick children. .

Settings and conduct

The researcher attended the oncology department of the Tabriz Children's Hospital and obtaining consent from the children and parents to participate in the research, the children who, according to the doctor's opinion and after the visit by him, need IT/ LP will select them by available sampling method .Due to the aromatic nature of clove oil and the ability to differentiate between clove oil and sweet almond oil through smell, and blinding in this study is only done for the analyst (statistical consultant).Massage with oils will be performed in the intervention groups for 5 minutes and the evaluation of the variables will be performed 20 minutes before and 3 minutes after the intervention.

Participants/Inclusion and exclusion criteria

Entry requirements: Definite diagnosis of cancer and hospitalization in the ward , Prescribing LP and receiving IT , Child aged 7 to 11 years Non-entry : The order to receive midazolam or other sedatives before the procedure. The child's restlessness and intolerance of research conditions. Loss of consciousness and lack of awareness of time, place and person. Severely ill and end-stage child. The need to observe contact precautions. Fever, risk of bleeding (platelet count less than 20,000), leukopenia

Intervention groups

Intervention group 1 effleurage massage with clove oil and intervention group 2 effleurage massage with sweet almond oil and the control group will only receive routine ward care.

Main outcome variables

pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230428058019N1**

Registration date: **2023-05-25, 1402/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-25, 1402/03/04**

Update count: **0**

Registration date

2023-05-25, 1402/03/04

Registrant information

Name

Fatemeh Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3322 6084

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-07, 1402/02/17

Expected recruitment end date

2023-08-08, 1402/05/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	and participants, and blinding in this study is only done for the analyst (statistical consultant). will be done, in such a way that they will only know the studied groups in the form of a and b and they will not know which participant will receive which intervention.
Scientific title The effect of effleurage massage with clove oil on IT/LP pain and anxiety among children with cancer: A randomized clinical trial.	Placebo Used
Public title The effect of massage with clove oil on pain and anxiety caused by IT/LP	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Definitive diagnosis of cancer and hospitalization in the ward . Prescribing LP and receiving IT Children aged 7 to 11 years Exclusion criteria: 1. The order to receive midazolam or other sedatives before the procedure 2. The child's restlessness and intolerance of research conditions 3. Loss of consciousness and lack of awareness of time, place and person 4. Severely ill and end-stage child 5. The need to observe contact precautions 6. Fever, risk of bleeding (platelet count less than 20,000), leukopenia 7. Inability to communicate verbally (deafness) and vision disorders and physical defects, Down's syndrome and genetic diseases that disrupt the expression and experience of pain. Having a wound, fracture, infection, redness and abnormal swelling in the massage area 8. People undergoing IT/LP for the first time. History of allergy to clove and sweet almond oil	Secondary Ids empty
Age From 7 years old to 11 years old	Ethics committees 1 Ethics committee Name of ethics committee Research Ethics Committee of Tabriz University of Medical Sciences Street address Resalat, No. 66, Koche Eskoi, Sosangerd Street City Tabriz Province East Azarbaijan Postal code 5178763914
Gender Both	Approval date 2022-01-11, 1400/10/21 Ethics committee reference number IR.TBZMED.REC.1400.1035
Phase 3	
Groups that have been masked • Data analyser	Health conditions studied 1 Description of health condition studied cancer ICD-10 code C90 ICD-10 code description Multiple myeloma and malignant plasma cell neoplasms
Sample size Target sample size: 39	Primary outcomes 1 Description pain Timepoint The pain variable will be evaluated 20 minutes before the intervention and 3 minutes after the intervention. Method of measurement visual analog scale of pain
Randomization (investigator's opinion) Randomized	
Randomization description The random allocation of participants to each of the study groups and the order of their placement in the groups will be done using the table of random numbers created with the Random Sample Numbers software by the respected Professor of Statistics. The participants will be selected using the available sampling method and will be divided into each group (intervention 1 and 2 and control (without intervention)) by random allocation using the random block method with the software. RAS will be generated.	2 Description
Blinding (investigator's opinion) Single blinded	
Blinding description Due to the aromatic nature of clove oil and the ability to differentiate between clove oil and sweet almond oil through smell, blinding is not possible for the researcher	

anxiety

Timepoint

The anxiety variable will be evaluated 20 minutes before the intervention and 3 minutes after the intervention.

Method of measurement

Children's Anxiety Meter-Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: 1 Working method in intervention group 1 (Effleurage massage group with clove oil) In addition to receiving routine care, this group received effleurage massage with clove oil, which has an analgesic effect to relieve the pain caused by IT/LP. Effleurage massage was performed 15 minutes before IT/LP for 5 minutes. 20 minutes before the child was taken to the procedure room for IT/LP and before the massage therapy, how to use the VAS pain and CAM anxiety measurement tool was explained to the child, and the child's pain and anxiety scores were evaluated based on the tools mentioned was measured. After completing the three-part tool including demographic questionnaire, VAS pain measurement tool and CAM anxiety measurement tool, the patient's basic pain and anxiety before IT/LP procedure and massage intervention were measured and determined. Then, respecting his privacy, the child was placed in a comfortable position on the bed in his room. The waist area was uncovered. Before starting the massage, the hands were warmed and slippery with oil and placed on the skin of the desired area. Then two-handed efflorescence massage was applied using palms and fingers in circular and linear motions in the direction of blood flow from the bottom to the heart and applying low pressure with surface rubbing for 5 minutes depending on the child's tolerance. For massage, clove oil from Shefai Kurdistan Company was used in the amount of 3-4 cc per massage (one third of the dose used in adults for pain relief according to the study of Rahmayanti⁴⁵). After the massage, 15 minutes were given for the local absorption of the oil and the child was placed in a comfortable position on his bed. After 15 minutes of the massage, the child was taken to the procedure room and the IT/LP procedure was performed on him by the doctor. 3 minutes after the completion of IT/LP, according to the general state of the child and before the child leaves the procedure room, the pain score experienced by the child during IT/LP using the VAS tool and the anxiety score experienced during the IT/LP procedure LP was evaluated and determined using the CAM tool.

Category

Treatment - Drugs

2

Description

Intervention group: In intervention group 2 (Effleurage massage with sweet almond oil), this group also received exfoliation massage with sweet almond oil in addition to receiving routine care. Massage was done 15 minutes before IT/LP for 5 minutes. According to the study of Batalha⁴⁰, sweet almond oil, which does not have many analgesic properties, was used as a placebo in intervention group 2. In this study, sweet almond oil was used by Barij Essans Pharmaceutical Company. Effleurage massage was performed 15 minutes before IT/LP for 5 minutes. 20 minutes before the child was taken to the procedure room for IT/LP and before the massage therapy, how to use the VAS pain and CAM anxiety measurement tool was explained to the child, and the child's pain and anxiety scores were evaluated based on the tools mentioned was measured. After completing the three-part tool including demographic questionnaire, VAS pain measurement tool and CAM anxiety measurement tool, the patient's basic pain and anxiety before IT/LP procedure and massage intervention were measured and determined. Then, respecting his privacy, the child was placed in a comfortable position on the bed in his room. The waist area was uncovered. Before starting the massage, the hands were warmed and slippery with oil and placed on the skin of the desired area. Then two-handed efflorescence massage was applied using palms and fingers in circular and linear motions in the direction of blood flow from the bottom to the heart and applying low pressure with surface rubbing for 5 minutes depending on the child's tolerance. For massage, 3-4 cc of sweet almond oil was used for each massage (one third of the dose used in adults for pain relief according to the study of Rahmayanti⁴⁵). After the massage, 15 minutes were given for the local absorption of the oil and the child was placed in a comfortable position on his bed. After 15 minutes of the massage, the child was taken to the procedure room and the IT/LP procedure was performed on him by the doctor. 3 minutes after the completion of IT/LP, according to the general state of the child and before the child leaves the procedure room, the pain score experienced by the child during IT/LP using the VAS tool and the anxiety score experienced during the IT/LP procedure LP was evaluated and determined using the CAM tool.

Category

Placebo

3

Description

Control group: Working method in the control group (without intervention), this group only received routine care before, during and after the IT/LP procedure, and no intervention was done by the researcher, and only the assessment of pain and anxiety before and after the procedure with tools It was mentioned and it was done and recorded in the mentioned times like the groups of intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahra Mardani Azari Children's Hospital

Full name of responsible person

Leila Valizadeh

Street address

Tabriz - the end of South Shariati St. - Faculty of Nursing and Midwifery in Tabriz

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fatemehrahimi028@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Leila Valizadeh

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Leila Valizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Demographic characteristics of subjects and pain and anxiety scores during the intervention

When the data will become available and for how long

"Starting the access period 6 months after printing the results"

To whom data/document is available

Researchers working in academia and industry

Under which criteria data/document could be used

It is possible to use the data with the permission of the researcher and citing the study.

From where data/document is obtainable

The full name of the responsible person Leila Valizadeh email fatemehrahimi028@gmail.com job position Professor Street Address Tabriz / Southern Shariati Street / College of Nursing and Midwifery City Tabriz State East Azarbaijan Country Islamic Republic of Iran Postal code 5178763914 Phone +98 41 3477 0649 Cellular phone +98 921 715 5629

What processes are involved for a request to access data/document

It takes about a month to send an email to the responsible person and review the request by him.(masculine)

Comments