Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 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

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Iran (Islamic Republic of)

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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

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

Public title
The effect of massage with clove oil on pain and anxiety caused by IT/LP

Purpose
Treatment

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

Age
From **7 years** old to **11 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **39**

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.

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 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.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

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

Approval date
2022-01-11, 1400/10/21

Ethics committee reference number
IR.TBZMED.REC.1400.1035

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

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

2

Description

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
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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
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Street address
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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 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