ISRCTN43067816 https://doi.org/10.1186/ISRCTN43067816

The massage in children with cancer: Effectiveness of a protocol

Submission date
18/12/2012

Recruitment status
No longer recruiting

Registration date
10/01/2013

Overall study status
Completed

Last Edited
10/01/2013

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Pain is an unpleasant and subjective experience that has sensorial, affective, cognitive, social and behavioral components. It is a major cause of human suffering and loss of quality of life. Health professionals have an ethical responsibility and a key role to play in order to provide effective pain control.
Unconventional therapies exist but there is little evidence about well they work. This is the case for children with cancer. The aim of this study is to evaluate how well three massage sessions will work in reducing pain in children with cancer aged between 10 and 18 years old.

Who can participate?
Children diagnosed with cancer and undergoing treatment (chemotherapy, antibiotics, or steroids). It excluded children not diagnosed, in terminal phase, in the first three days after surgery, in isolation from contact, with fever, bleeding risk and altered states of consciousness or cognitive disturbances.

What does the study involve?
Participants were randomly allocated to a treatment group or a control group.
In the treatment group, the treatment consisted in three massage sessions on alternate days during a week (day 1, 3 and 5). The massage technique included gliding movements, light compression and the use of heated sweet almond oil. Each session lasted between 20 and 30 minutes. The control group received usual care. All children received the same care, except the application of massage in the treatment group.

What are the possible benefits and risks of participating?
Study participants could benefit from better pain control and less interference of pain in their daily lives. There are no risks as long as the exclusion criteria are followed.
The study was conducted according to the Declaration of Helsinki of the World Medical Association. Written consent was provided by the child and the child's legal guardians.

Where is the study run from?
This study involved the Nursing School of Coimbra and Portuguese Oncology Institute of Porto (Portugal).

When is the study starting and how long is it expected to run for?
The study took place at the Portuguese Oncology Institute of Porto between November 2010 and March 2011.

Who is funding the study?
Portuguese Oncology Institute of Porto (Portugal)

Who is the main contact?
Professor Luís Batalha
batalha@esenfc.pt

Contact information

Type(s)
Scientific

Contact name
Prof Luís Batalha

Contact details
Escola Superior de Enfermagem de Coimbra
Av. Bissaya Barreto Ap. 7001
Coimbra
Portugal
3046-851
+351 239 487 200
batalha@esenfc.pt

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The massage in children with cancer: Effectiveness of a protocol a randomized controlled trial

Study objectives
The implementation of a protocol of three massage sessions on alternative days during a week reduces the pain and its interference in the activities of children (10 to 18 years), hospitalized with cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Committee for Health IPO-Porto (Comissão de Ética para a Saúde IPO-Porto), Portugal, 30 /09/2010, ref: 258/010

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Relief of pain in children with cancer through massage

Interventions
Children and adolescents hospitalized in a pediatric oncology department aged 10 to 18 years with a diagnostic disease and treatment (chemotherapy, antibiotics or steroids) were randomly divided into two groups (control and intervention).

The children in the intervention group (GI) were subjected to a protocol consisting of three massage sessions in alternative days, during a week (day 1, 3 and 5). The massage technique consisted of gliding movements, light compression and the use of heated sweet almond oil. Each session lasted between twenty and thirty minutes.

Control group (CG) received usual care.

Finally, the efficacy of the protocol was measured by analyzing the differences between the results at the beginning (day 0) and the results at the end of protocol (day 6) by evaluating the pain and their interference in the activities of children.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The pain is measured by using the Visual Analogue Scale (VAS), scored (0 = no pain, 10 = unbearable pain) and physical functioning, assessed by the Brief Pain Inventory scales (BPI), scored numerical rating scale (0 = without interferences in the activity, 10 = the maxim interference) at the beginning (day 0) and at the end of protocol (day 6).

Secondary outcome measures
Pain intensity by the Visual Analogue Scale (VAS) scored (0 = no pain, 10 = unbearable pain) was assessed in a break of half-hour at the beginning and the end of each session massage.

Overall study start date
01/11/2010

Completion date
30/03/2011

Eligibility

Key inclusion criteria
Children between 10 and 18 years old hospitalized in a pediatric department with a diagnostic with cancer and treatment (chemotherapy, antibiotics or steroids)

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Total participants 52 children. Intervention and control group consisting of 26 children each.

Key exclusion criteria
1. Children in terminal phase
2. The first three days after surgery
3. In isolation from contact with fever
4. Bleeding risk (platelet count less than 10 000)
5. Altered states of consciousness or cognitive disorders

Date of first enrolment
01/11/2010

Date of final enrolment

30/03/2011

Locations

Countries of recruitment
Portugal

Study participating centre
Escola Superior de Enfermagem de Coimbra
Coimbra
Portugal
3046-851

Sponsor information

Organisation
Nursing School of Coimbra (Escola Superior de Enfermagem de Coimbra) (Portugal)

Sponsor details
Av. Bissaya Barreto Ap. 7001
Coimbra
Portugal
3046-851
+351 239 802 850
esenfc@esenfc.pt

Sponsor type
University/education

Website
http://www.esenfc.pt

ROR
https://ror.org/03c3y8w73

Funder(s)

Funder type
Research organisation

Funder Name

Portuguese Oncology Institute of Porto [Instituto Português de Oncologia do Porto, Francisco Gentil, EPE (IPOPFG, E.P.E.)] (Portugal)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration