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Overshadowing as prevention of anticipatory nausea and vomiting

Submission date
30/04/2012

Recruitment status
No longer recruiting

Registration date
13/06/2012

Overall study status
Completed

Last Edited
25/10/2013

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims?
Nausea and vomiting are side effects that result from chemotherapy, which leads to enormous stress and strain on cancer patients. Other side effects may include reduced quality of life, strong weight loss or therapy avoidance. During treatment patients may learn to associate the hospitals environment (for example smells, sounds or even the sight of the clinic) with chemotherapy and develop additional side effects such as nausea and vomiting prior to infusion, called anticipatory nausea and vomiting. Despite medication anticipatory reactions occur in 30% to 59% of cases.
It should be possible to prevent such nausea and vomiting occurrences with a treatment called overshadowing. Overshadowing uses the principle that an unusual stimulus overlays usual stimuli. It can prevent a response to usual stimuli (such as hospital environments). The aim of the study is to examine the results of overshadowing on anticipatory nausea and vomiting in pediatric cancer patients.

Who can participate?
Participation is open to pediatric patients (4 years old and above) newly diagnosed with cancer. Participants cannot be included if they have mental health problems or gastrointestinal tract cancer.

What does the study involve?
Participants will be randomly allocated to one of two groups: two different types of candy tasting different prior to every chemotherapy infusion through three treatment cycles. Participants will have to describe levels of discomfort, anxiety, adherence to treatment and quality of life in logs and questionnaires.

What are the possible benefits and risks of participating?
No side effects are expected. Conventional drugs against nausea and vomiting (called antiemetic) remain available during the whole study. If overshadowing works as in preliminary studies, participants should experience less nausea and vomiting and this may reduce the use of antiemetic drugs.

Where is the study run from?
The study is planned as a single centre study at University Hospital Kiel, Germany (Department of Pediatrics). If recruitment of participants turns out to be difficult, the study will also take place at the University Hospital of Lübeck, Germany.

When is the study starting and how long is it expected to run for?
The study is anticipated to start on 01/06/2013 and to end on 30/11/2015.

Who is funding the study?
The study is initially funded by University Medical Center Schleswig-Holstein, Campus Kiel, Germany. Additional external funding is in progress.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
2012-01-ANV-OS

Study information

Scientific Title
Overshadowing as prevention of anticipatory nausea and vomiting in pediatric cancer patients - a randomized placebo controlled trial

Study objectives
Overshadowing can prevent anticipatory nausea and vomiting

Ethics approval required
Old ethics approval format

Ethics approval(s)

Medical Faculty Ethics Committee of University of Kiel, Germany, 06 March 2012, ref: A168/11

Primary study design
Interventional

Study design
Randomized placebo controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pediatric oncology

Interventions
A randomized, double-blinded, placebo-controlled study in pediatric cancer patients treated with at least 3 chemotherapy cycles - Two arms: the experimental group will get salient candy and the control group flavorless placebo tablets prior to every infusion of chemotherapy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
anticipatory nausea and vomiting (via patient administered discomfort logs)

Key secondary outcome(s)
1. Post-treatment nausea and vomiting (via patient administered discomfort logs)
2. Quality of life (via patient administered KINDL-R questionnaire), state-anxiety (via patient administered KAT-II, form P / STAI) and adherence (via ratings by medical personnel)
3. Relation between prevalence of post-treatment and anticipatory nausea and vomiting
4. Applicability of the overshadowing treatment in the hospitals daily routine

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. New diagnosis
2. German speaking
3. Age from 4 years
4. Receiving 3 chemotherapy cycles
5. Intervals of 7 days in-between the single chemotherapy cycles

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Sex
All

Key exclusion criteria
1. CNS or gastrointestinal tract cancer
2. Mental restrictions
3. Recurrent cancer
4. Prior radiotherapy

Date of first enrolment
01/06/2013

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
Germany

Study participating centre
General Pediatrics Department [Klinik für Allgemeine Pädiatrie]
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Sponsor information

Organisation
University of Kiel (Germany)

ROR
https://ror.org/04v76ef78

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/04/2013		Yes	No