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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?
Dr Friedemann Geiger
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Friedemann Geiger

### Contact details
General Pediatrics Department [Klinik für Allgemeine Pädiatrie]
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24105

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Study design
Randomized placebo controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## 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
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 measure
anticipatory nausea and vomiting (via patient administered discomfort logs)

## Secondary outcome measures
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

### Overall study start date
01/06/2013

### 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

### Age group
Child

### Lower age limit
4 Years

### Sex
Both

### Target number of participants
50

### 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]**
Kiel
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24105

# Sponsor information

**Organisation**
University of Kiel (Germany)

**Sponsor details**
c/o Prof. Dr. Martin Schrappe
General Pediatrics Department [Klinik für Allgemeine Pädiatrie]
University Hospital of Schleswig-Holstein
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Germany
24105

**Sponsor type**
University/education

**Website**
http://www.uni-kiel.de/

**ROR**
https://ror.org/04v76ef78

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# 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

### Study outputs

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