

# Overshadowing as prevention of anticipatory nausea and vomiting

<b>Submission date</b> 30/04/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/10/2013	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
f.geiger@uksh.de

## Contact information

### Type(s)

Scientific

### Contact name

Dr Friedemann Geiger

### Contact details

General Pediatrics Department [Klinik für Allgemeine Pädiatrie]  
University Hospital of Schleswig-Holstein  
Schwanenweg 20  
Kiel  
Germany  
24105

## 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)

## **Study design**

Randomized placebo controlled trial

## **Primary study design**

Interventional

## **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]

Kiel

Germany

24105

**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?
<a href="#">Protocol article</a>	protocol	20/04/2013		Yes	No