

# Comparison two methods of treatment of mouth ulcer in childhood cancer patients study design: Randomized parallel trial

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<b>Registration date</b> 07/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/04/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chemotherapy is a type of cancer treatment which works by killing the cancer cells so that they can't spread. Although it is an effective cancer treatment, it does have side effects. The drugs used in chemotherapy cannot distinguish between the fast-growing cancer cells and healthy types of fast-growing cells in the body. One of the most common cells affected are part of the mucous membrane, in a condition known as mucositis. The mucous membrane acts to line the parts of the body which come into contact with air, such as in the mouth and digestive system (gastrointestinal tract). Oral mucositis is the most common type of mucositis in cancer patients, and can lead to a number of problems, such as mouth ulcers, pain, increased risk of infection and nutritional problems due to difficulty swallowing. There are a number of ways to help treat patients suffering from oral mucositis. This study aims to compare how effective an oral aid gel (zytee) which is used to treat mouth ulcers, with taking granulocyte-colony stimulating factor (GCSF) which helps to increase the number of white blood cells that are released into the blood, helping to fight infection.

### Who can participate?

Children with cancer, on chemotherapy treatment with oral mucositis.

### What does the study involve?

Participants are randomly divided into one of two groups. The first group are treated with the oral aid (zytee gel), and the second group are treated with granulocyte-colony stimulating factor (GCSF), which is taken in oral form.

### What are the possible benefits and risks of participating?

Possible benefits of participating are increasing knowledge about oral health, as well as patients receiving treatment free of charge. There are no risks of participating in the study,

### Where is the study run from?

Hospital Universiti Sains Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?

April 2013 to April 2016

Who is funding the study?

Hospital Universiti Sains Malaysia (Malaysia)

Who is the main contact?

Dr Malid Alshannuki

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Randomized controlled trial of oral GCSF versus oral aid for treating oral mucositis in patients with childhood cancer receiving chemotherapy

### Study objectives

There are significance differences of the outcomes of treating oral mucositis between oral GCSF and oral aid groups .

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

Ethics Committee at Universiti Sains Malaysia, ref: USMKK/PPP/JEPeM[261.3(16)]

**Study design**

Single-centre randomized parallel trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Oral mucositis

**Interventions**

Medication (routinely used in the pediatric Oncology ward in HUSM) will be given three times daily (morning, evening, and night) until the oral mucositis resolved.

Block randomization will be used for randomization. The basic idea of block randomization is to divide potential patients into  $m$  blocks of size  $2n$ , randomize each block such that  $n$  patients are allocated to A and  $n$  to B, then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used. Example: Two treatments of A, B and Block size of  $2 \times 2 = 4$

Group A: Oral aid (zytee) Composition: Choline salicylate and benzalkonium chloride.

Group B : Oral granulocyte colony stimulating factor GCSF (0.1ml).

Possible treatment allocations within each block are:

1. AABB
2. BBAA
3. ABAB
4. BABA
5. ABBA
6. BAAB

**Intervention Type**

Drug

**Drug/device/biological/vaccine name(s)**

1. Oral aid (zytee) Composition: Choline salicylate and benzalkonium chloride
2. GCSF (granulocyte colony stimulating factor)

**Primary outcome measure**

Primary outcomes as of 18/04/2017:

1. Time to healing of oral mucositis is measured using WHO oral toxicity scale at baseline and daily until oral mucositis resolved at 24, 48, 72, 96, 120, 144, and 168 hours
2. Improvement in the absolute neutrophil count is measured using results of absolute neutrophil count in full blood count at baseline and one week

Original primary outcome:

Healing of the oral mucositis between oral GCSF and oral aid, measured at baseline, day 3 and day 7.

### **Secondary outcome measures**

Secondary outcome as of 18/04/2017:

1. Relief of oral pain and dysphagia is measured using WHO oral toxicity scale at baseline, 3 and 7 days

Original secondary outcomes:

1. Relief the pain of oral mucositis also measured at baseline, measured at baseline, day 3 and day 7. Who oral toxicity scale will be used to assess the severity the oral toxicity are ranked on a scale of 1 to 4, with 1 being minor soreness and painless, 2 is painful erythema, edema, or ulcers but able to eat ,3 is painful erythema, edema, or ulcers but unable eat,and 4 If there is sever pain and requirement for parenteral or enteral support
2. Improvement in absolute neutrophile count (ANC) measured pre (at baseline) and post (on day 7).

**Overall study start date**

01/04/2013

**Completion date**

01/04/2016

## **Eligibility**

**Key inclusion criteria**

1. Aged 3-12 years
2. Have oral mucositis
3. On chemotherapy treatment

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

3 Years

**Upper age limit**

12 Years

**Sex**

Both

**Target number of participants**

76

**Key exclusion criteria**

1. Other causes of oral ulcer such as trauma and CT disease
2. Cancer patient who is not under chemotherapy

**Date of first enrolment**

01/04/2013

**Date of final enrolment**

01/04/2016

## **Locations**

**Countries of recruitment**

Malaysia

**Study participating centre**

**Hospital Universiti Sains Malaysia**

15200 Kota Bharu

Kelantan

Kota Bharu

Malaysia

16150

## **Sponsor information**

**Organisation**

Hospital Universiti Sains Malaysia

**Sponsor details**

Pediatric Oncology School of Medical Sciences

University Sains Malaysia Health Campus

Kota Bharu

Malaysia

16150

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/0090j2029>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Hospital Universiti Sains Malaysia

## **Results and Publications**

### **Publication and dissemination plan**

We are planning to publish the whole study (randomized controlled trial of oral GCSF vs. oral aid in treating oral mucositis in childhood cancer patients receiving chemotherapy), but if the results are significant we may separate them into 3 papers (in terms of time of heal, relief of oral pain, and improvement of ANC).

### **Intention to publish date**

01/10/2016

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration