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

Submission date 11/08/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/10/2015	**Overall study status** Completed	
Last Edited 18/04/2017	**Condition category** Oral Health	

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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 size2n, 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 x 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(s)
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.

Key secondary outcome(s))

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).

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
12 years

Sex
All

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
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16150

Sponsor information

Organisation
Hospital Universiti Sains Malaysia

ROR
https://ror.org/0090j2029

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Universiti Sains Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration