

# Benefit of prebiotic in reducing loose motions among cancer patients experiencing radiotherapy

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>31/10/2019   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>09/11/2019 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>04/08/2020       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Radical radiation therapy is commonly used for the treatment of pelvic cancers. The most common acute side effect of radiation is diarrhea, which can affect up to 80% of patients treated. One of the clinical complications that occurs following an inflammatory response to irradiation is a modification of the intestinal microflora. Gastrointestinal symptoms usually begin the second week of treatment and can lead to other problems such as malnutrition, abdominal pain, fecal incontinence, tenesmus, dehydration, weakness, reduced quality of life, increased cost of care, and delayed treatment completion. The aim of this study is to find out whether partially hydrolysed guar gum (PHGG) can reduce diarrhea occurrence among cancer patients undergoing pelvic radiation.

### Who can participate?

Cancer patients with pelvic cancers scheduled for external beam radiotherapy (EBRT) treatment

### What does the study involve?

Participants are randomly allocated to receive either 10 g PHGG twice daily or 10 g maltodextrin (placebo) twice daily. Duration of supplementation is 28 days: 14 days before radiation and 14 days during treatment. Participation involves body measurements (weight, height and mid upper arm circumference), blood pressure, temperature and heart rate measurements, collection of blood and stool samples, and symptoms charting.

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

Participants will know their current body measurements, vital signs, liver profile, renal profile, full blood count level and dietary intake. Information from this study will have an important bearing on health policy as guidelines for dietary treatment of pelvic radiation among cancer patients undergoing pelvic radiotherapy in the Ministry of Health. Selected participants will undergo the standard procedure similar to the current practice by the Ministry of Health. Therefore, there will be minimal risk in taking part in this study.

Where is the study run from?  
Hospital Sultan Ismail Johor Bahru (Malaysia)

When is the study starting and how long is it expected to run for?  
April 2015 to April 2016

Who is funding the study?  
Bio Scenergy Sdn Bhd

Who is the main contact?  
Prof. Suzana Shahar  
suzana.shahar@ukm.edu.my

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Suzana Shahar

**Contact details**  
Faculty of Health Sciences  
Universiti Kebangsaan Malaysia  
Jalan Raja Muda Abdul Aziz  
Kuala Lumpur  
Malaysia  
50300  
+603 (0)9289 7602  
suzana.shahar@ukm.edu.my

## Additional identifiers

**Protocol serial number**  
NMRR-14-1501-23172 (IIR)

## Study information

**Scientific Title**  
Efficacy of partially hydrolysed guar gum (PHGG) in reducing risk of diarrhea among cancer patient undergoing pelvic radiation

**Study objectives**  
Does PHGG can reduce diarrhea occurrence among cancer patient undergoing pelvic radiation?

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 08/04/2015, Medical Research Ethics Committee (MREC)/MOH Research Grants (MRG) / Publication NIH Secretariat (Ministry of Health Malaysia, c/o Institute for Health Management, Block A, Kompleks Institut Kesihatan Negara (NIH), No 1 Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam, 40170 Shah Alam, Malaysia; Tel: +603 (0)3-3362 8888/8205; Email: nihsec@moh.gov.my), ref: NMRR-14-1501-23172 (IIR)

## **Primary study design**

Interventional

## **Study design**

Double-blind randomised controlled trial

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Cancer patient (endometrium, cervix, colon, rectum and prostate) undergoing pelvic radiation treatment

## **Interventions**

Eligible patients were allocated randomly (Random Allocation Software Ver 1.0 May 2004) to receive either 10 g twice daily PHGG or 10 g twice daily maltodextrin (placebo). Duration of supplementation was 28 days, e.g. 14 days pre radiation and 14 days during treatment.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

Measured at baseline, day 7 (for microbiome growth only), day 14, day 28 and day 45:

1. Diarrhea incidence and frequency classified according to the National Cancer Institute Common Terminology Criteria (NCI-CTC); a reference of cancer patient's managements Ministry of Health Malaysia 2017 (MOH Systemic Therapy Protocol 2016)
2. Stool formations recorded daily by patients based on Bristol Stool Charts

## **Key secondary outcome(s)**

Measured at baseline, day 7 (for microbiome growth only), day 14, day 28 and day 45:

1. Patient's self-collected fecal samples preserved in Stool Nucleic Acid Collection and Transport Tubes (Norgen, Canada) at 4°C until further processing. Fecal DNA extracted using Stool DNA Extraction kit (Qiagen, Germany). DNA samples assessed for their quality and quantity using NanoDrop Spectrophotometer (Thermo Scientific, UK). DNA samples stored at -20°C until further use.
2. Quantification of Bifidobacterium spp. and all bacteria cells based on copy number of 16s rDNA region performed using probe-based qPCR assay by 1st Base Laboratories Sdn Bhd (604944-X). All reactions performed in a 25 µL reaction system of (Thermo Scientific™ Maxima Probe qPCR Master Mix (2X)
3. Comprehensive nutritional status assessed using Scored Patient-Generated Subjective Global Assessment (PG-SGA)
4. Quality of Life (QoL) assessed using EORTC QLQ-C30 version 3.0 questionnaire

## **Completion date**

08/04/2016

## Eligibility

### Key inclusion criteria

Cancer patient with pelvic cancers scheduled for external beam radiotherapy (EBRT) treatment as an outpatient or inpatient with EBRT dose 40 Gray and above, 180-220 cGy per fraction

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 Years

### Sex

All

### Total final enrolment

30

### Key exclusion criteria

Patients receiving enteral or parenteral nutrition or terminally ill

### Date of first enrolment

30/05/2015

### Date of final enrolment

30/12/2015

## Locations

### Countries of recruitment

Malaysia

### Study participating centre

**Hospital Sultan Ismail Johor Bahru**

Jalan Mutiara Emas Utama, Taman Mount Austin

Johor Bahru

Malaysia

81100

# Sponsor information

## Organisation

Bio Scenergy Sdn Bhd

## Funder(s)

### Funder type

Industry

### Funder Name

Bio Scenergy Sdn Bhd

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dzairudzee Rosli (dzai8558@gmail.com). Data obtained from the subject of the survey form is recorded and stored in accordance with the procedure of recording data by local law (Ministry of Health Malaysia). Archiving data is confidential and will be kept from unauthorized parties. Data and documents used throughout the study retained until five years after the study ended.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/02/2021   | 04/08/2020 | Yes            | No              |