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

Submission date
31/10/2019

Recruitment status
No longer recruiting

Registration date
09/11/2019

Overall study status
Completed

Last Edited
04/08/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 occurence 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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 occurence 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)

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

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?
Results article	results	01/02/2021	04/08/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes