Supplemental prophylactic intervention for chemotherapy-induced nausea and emesis (spice) trial: Protocol for a multi-centre double-blind placebo-controlled randomized trial

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Protocol for a double-blind placebo-controlled randomized trial

Ginger for chemotherapy-induced nausea and vomiting?

Introduction

Ginger may have the potential to act as an adjuvant therapy for chemotherapy-induced nausea and vomiting (CINV). Despite advances in anti-cancer treatments and anti-emetic medication, low risk and cost-effective therapies to improve nausea-related QoL, symptom management and ultimately the survival of patients undergoing chemotherapy are needed.

Research aim: To assess the efficacy (reduced incidence and severity of CINV, enhanced quality of life), safety, cost-effectiveness, and impact on gut microbiota of a standardized adjuvant ginger root supplement.

Eligibility Criteria

INCLUDED

- Chemotherapy-naive
- Moderately to highly emetogenic CTX
- Single-day CTX regimen
- Age >18 years
- English speaking
- Adequate physical function
- Ability to safely swallow capsules
- Cognitive ability to understand study purpose and adhere to study

EXCLUDED

- Concurrent radiotherapy
- Concurrent use of ginger in food-supplement/drinks
- History of adverse event to ginger
- Prescribed anti-coagulants, NSAIDs or hypoglycaemics
- Self-prescribed nausea therapies
- Chronic alcohol use (>14 standard drinks per week)
- Experiencing nausea and/or vomiting for reasons other than CTX
- Gall stones or liver disease
- Thrombocytopenia
- Pregnant or lactating women

Study Procedure

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<td>Concurrent ginger intake</td>
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<td>Adverse events</td>
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<td>Stool swab sample</td>
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Results

- N=38 recruited from Site A since commencing October 2017. Recruitment expected to commence at Site B July 2018.
- 85% response rate.
- 55% female; mean age 59 ± 12 years; 36% lung cancer, 21% breast, 12% lymphoma, 24% other.
- No reported serious adverse events relatable to the study intervention.

Outcomes

This study, aimed to be completed in April 2019, will:

- evaluate the safety of ginger supplementation;
- examine the ginger formulation and dosing regimen needed;
- control potential confounders;
- indicate the capacity of ginger to ameliorate CINV-related effects such as fatigue and compromised nutrition.

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