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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<tr>
<th>Timepoint</th>
<th>T0</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Pre-CTX</td>
<td>Day before CTX</td>
<td>Day of CTX</td>
<td>4 days post-CTX</td>
<td>5-8 days post-CTX</td>
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<tr>
<td>CTX cycle (C)</td>
<td>1 only</td>
<td>1 - 3</td>
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Screened and consented ✓
Participant characteristics ✓
Delivery of supplements ✓
Delivery of Participant Booklet ✓
Nutrition status (Scored PG-SGA) ✓ (C2-3)
Supplements consumed ✓ ✓
CIN-related QoL (FUE-5D) ✓
Global QoL (EQ-5D-5L) ✓
Antipr nonsense and vomiting ✓
Nausea and vomiting (MAT) ✓
Depression and anxiety (HADS) ✓
Fatigue (FACIT-F) ✓ ✓
Health service use ✓ (C3)
Blinding and adherence ✓
Concurrent ginger intake ✓ ✓ ✓ ✓
Adverse events ✓
Stool swab sample ✓

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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