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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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.

Intervention

- **Study Design**: Multi-centre double-blind placebo-controlled randomized trial.
- **Recruitment**: Two hospitals in Brisbane, Queensland, Australia up until April 2019. Target sample size: N=300.
- **Supplementation Schedule**: 4x 300mg over-encapsulated capsules of ginger per day (1.2g ginger/60mg gingerols per day) OR 4x 300mg over-encapsulated capsules of placebo per day (1.2g inner filler microcrystalline cellulose) → 1x capsule every 3-4 hours → capsules consumed for 5 days → commencing Day 1 of CTX Cycle 1 → For Cycles 1 to 3.
- **Alterations to Standard Care**: No changes to standard care. Use of anti-emetic medications prescribed by medical teams permitted during the trial.

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

<table>
<thead>
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<th>Timepoint</th>
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<td>Pre-CTX</td>
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<td>5-8 days post-CTX</td>
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CTX cycle (C)

- 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-5DR) ✓ ✓
- Global QoL (EQ-5D-5L) ✓ ✓
- Antisipatory nausea 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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