

# Ginger (Zingiber officinale) as anti-emetic prophylaxis for chemotherapy-induced nausea and vomiting

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<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/03/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Kerry Guile

**Contact details**  
Oncology Dept  
Jenner Wing Level 2  
St George's Hospital  
Blackshaw Road  
Tooting  
London  
United Kingdom  
SW17 0QT

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

Ginger (*Zingiber officinale*) as anti-emetic prophylaxis for chemotherapy-induced nausea and vomiting

### Study objectives

To establish the antiemetic efficacy of ginger (*Zingiber officinale*) in addition to standard antiemetic therapy for highly emetogenic cancer chemotherapy.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled open-label trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

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

Signs and Symptoms: Nausea and vomiting

### Interventions

A single supply of commercially available ginger capsules will be purchased. Patients in the study group will receive 550mg orally 3x a day for 5 days. 1st dose will be administered 1 hour prior to the first dose of chemotherapy. Trial medication will be used during the first cycle of chemotherapy only.

Study protocol: The study will recruit patients receiving FEC chemotherapy or any regimen containing cisplatin at 50mg/m<sup>2</sup> or more in a single dose. Patients will be randomly and evenly allocated into 2 groups.

Group 1 - 59 patients receiving standard antiemetic therapy.

Group 2 - 59 patients receiving standard therapy plus ginger. Randomisation will be performed by the Clinical Trials Support Unit, Institute of Cancer Research.

**Regimens:** The chemotherapy unit at St George's Hospital has had a formal antiemetic policy in operation since 1998. Patients receiving FEC or cisplatin-based chemotherapy are routinely offered 'Level 4' antiemetic prophylaxis.

**Schedule of clinical activity:** Patients will be given a diary card to record nausea and episodes of vomiting for 5 days following administration of chemotherapy. Investigators will independently record episodes of nausea or vomiting on the Case Report Form. The use of salvage antiemetics will also be noted. Both nausea and vomiting will be graded according to the NCI common toxicity criteria.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Ginger (Zingiber officinale)

### **Primary outcome measure**

Total antiemetic control (no nausea or vomiting during the study period)

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/05/2003

### **Completion date**

01/05/2005

## **Eligibility**

### **Key inclusion criteria**

118 cancer patients

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

118

### **Key exclusion criteria**

1. Any prior chemotherapy
2. Anticipatory nausea/vomiting
3. Concurrent use of products containing ginger or ginger preparations
4. Concurrent use of any other experimental drugs
5. Clinical or radiological evidence of cerebral metastases
6. Clinical or radiological evidence of intestinal obstruction; any profound metabolic disturbance liable to cause nausea and vomiting (hypercalcaemia, diabetic ketoacidosis etc)
7. Any history of hypersensitivity to ginger
8. Any condition precluding the use of standard antiemetic therapy

**Date of first enrolment**

01/05/2003

**Date of final enrolment**

01/05/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St George's Hospital**

London

United Kingdom

SW17 0QT

## Sponsor information

**Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

St George's Healthcare NHS Trust (UK), NHS R&D Support Funding

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration