

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/03/2020	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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Additional identifiers

Protocol serial number
N0236151198

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

Study type(s)

Treatment

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/m² 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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/05/2005

Eligibility**Key inclusion criteria**

118 cancer patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

St George's Hospital

London

United Kingdom

SW17 0QT

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

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

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration