ISRCTN66392513 https://doi.org/10.1186/ISRCTN66392513

A study to investigate the effect of hypnotically induced nausea on gastric emptying rate of a standard meal in normal healthy volunteers

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/04/2018	Signs and Symptoms	[ ] 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
N0226111711

Study information

Scientific Title
A study to investigate the effect of hypnotically induced nausea on gastric emptying rate of a standard meal in normal healthy volunteers

Study objectives
To assess the effect of hypnotically induced nausea on gastric emptying rate of a standard meal in normal healthy volunteers and to validate a new technique for the induction of nausea in a laboratory setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo-controlled crossover study trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions
A randomised, placebo controlled crossover study design will be used - each subject will have their gastric emptying rate assessed on one visit in the control state and following hypnotic induction of nausea on the other.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To determine whether hypnotically induced nausea delays gastric emptying in normal healthy control subjects.

Key secondary outcome(s))
Not provided at time of registration

Completion date
21/01/2004

Eligibility

Key inclusion criteria
Eight healthy volunteers determined by detailed medical history, physical examination, electrocardiogram (ECG) and negative pregnancy test.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/05/2002

Date of final enrolment
21/01/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Withington Hospital
Manchester
United Kingdom
M20 2LR

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South Manchester University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration