

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/04/2018	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised cross over trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

To determine whether hypnotically induced nausea delays gastric emptying in normal healthy control subjects.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2002

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

Age group

Adult

Sex

Both

Target number of participants

8

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

England

United Kingdom

Study participating centre
Withington Hospital
Manchester
United Kingdom
M20 2LR

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South Manchester University Hospitals NHS Trust (UK)

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