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Nutrient modulation of sensory responses of the human oesophagus

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/02/2018	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Simon Lal

Contact details
Gastroenterology
Clinical Sciences Building
Hope Hospital
Stott Lane
Salford
United Kingdom
M6 8HD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0217101260

Study information

Scientific Title
Nutrient modulation of sensory responses of the human oesophagus

Study objectives
To determine whether intragastric or intraduodenal infusion of cholecystokinin (CCK)-releasing fatty acid (C12 or C14) modifies the threshold at which sensations are experienced in response to different oesophageal stimuli, when compared to a non-CCK-releasing fatty acid (C10 or C8).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Sensory responses of the human oesophagus

Interventions
Extended pilot study consisting of a series of randomised controlled studies.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To confirm or refute the hypothesis that fatty acids have a differential effect on oesophageal sensations.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2001

Completion date
31/05/2004

Eligibility

Key inclusion criteria
Healthy male or female volunteers aged 20 - 60 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2001

Date of final enrolment
31/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hope Hospital
Salford
United Kingdom
M6 8HD

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
Salford Royal 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