Nutrient modulation of sensory responses of the human oesophagus

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
05/02/2018	Digestive System	Record updated in last year

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