

Nutrient modulation of sensory responses of the human oesophagus

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 05/02/2018	Condition category Digestive System	<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
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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/05/2004

Eligibility**Key inclusion criteria**

Healthy male or female volunteers aged 20 - 60 years

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Hope Hospital

Salford

United Kingdom

M6 8HD

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Salford Royal Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration