

Determination of safety of patients drinking before gastroscopy

Submission date 11/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/02/2013	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
N0500103996 and N0300106567

Study information

Scientific Title

Acronym

GaFFA

Study objectives

To determine the clinical equivalence of a shortened and conventional fluid fasting time in endoscopy patients in levels of gastric volume and pH.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Blackburn Hyndburn and Ribble Valley National Health Service Trust Local Research Ethics Committee, November 2001 (reference number: NJ/AK/LRECBHRV061).

Study design

Double-blind randomised controlled clinical equivalence trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Digestive system disease requiring diagnostic endoscopy

Interventions

1. Study group: six-hour food fast, two-hour water fast
2. Control group: standard six-hour food and fluid fast

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Gastric volume
2. pH

Key secondary outcome(s)

1. Thirst
2. Anxiety

Completion date

31/03/2006

Eligibility**Key inclusion criteria**

1. Aged 18 to 80 years
2. Undergoing routine diagnostic out-patient endoscopy
3. American Society of Anesthesiologists (ASA) grade one to two

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. ASA grade three or greater
2. Previous gastric or duodenal surgery
3. Dysphagia
4. Patients taking acid suppressing medications
5. Diabetes

Date of first enrolment

18/06/2002

Date of final enrolment

31/03/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Gastroenterology

Lancashire

United Kingdom

BB2 3LR

Sponsor information

Organisation

National Health Service Executive (UK)

ROR

<https://ror.org/02wnqcb97>

Funder(s)**Funder type**

Government

Funder Name

National Health Service Executive (UK) (ref: RDO/28/3/21)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration