ISRCTN98555764 https://doi.org/10.1186/ISRCTN98555764

Determination of safety of patients drinking before gastroscopy

Submission date 11/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/03/2006	**Overall study status** Completed	
Last Edited 15/02/2013	**Condition category** Digestive System	

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
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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