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

Contact name
Ms Lesley Miller

Contact details
Department of Gastroenterology
Blackburn Royal Infirmary
Bolton Road
Blackburn
Lancashire
United Kingdom
BB2 3LR
+44 (0)1254 294222

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure

1. Gastric volume
2. pH

Secondary outcome measures
1. Thirst
2. Anxiety

Overall study start date
18/06/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
508

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
England

United Kingdom

Study participating centre
Department of Gastroenterology
Lancashire
United Kingdom
BB2 3LR

Sponsor information

Organisation
National Health Service Executive (UK)

Sponsor details
Institute for Public Health Research and Policy
University of Salford
4th Floor
Humphrey Booth House
Hulme Place
The Crescent
Salford
United Kingdom
M5 4QA

Sponsor type
Government

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

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