ISRCTN13858956 https://doi.org/10.1186/ISRCTN13858956

Drinking a solution prior to gastroscopy improves the view

Submission date	Recruitment status	[_] Prospectively registered
24/01/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2016	Digestive System	

Plain English summary of protocol

Background and study aims
Diagnostic gastroscopy (camera examination of the gullet and stomach) provides a unique opportunity to answer specific diagnostic questions and identify lesions which develop into problems such as cancer at an early stage. There is, however, evidence to show that in the UK and the West there is a significant miss rate when assessing the identification of these early lesions. Stomach mucus and swallowed saliva can make it difficult to view the inner lining of the gullet and stomach during this procedure. Two commonly used medications (simethicone and N-acetylcysteine [NAC]) have been shown to be of potential benefit in clearing this obscuring mucus. We are trying to find out whether the use of a preparatory drink containing NAC and simethicone will improve visibility during gastroscopy.

Who can participate?
All patients aged 18 or over attending for gastroscopy are eligible to take part.

What does the study involve?
Patients undergo the standard preparation for gastroscopy at home (clear fluids only for 6 hours then nil by mouth for 2 hours). Patients are then randomly allocated into three groups.
1. Control no further intervention.
2. Water patients will drink sterile water 15-20 minutes before gastroscopy.
3. Solution patients will drink sterile water containing NAC and simethicone 15-20 minutes before gastroscopy.
The endoscopist and the nursing staff are unaware of the preparation used. During the gastroscopy the visibility is assessed by documenting the amount of water required to flush away mucus to enable a clear view of the lining of the stomach/gullet at specified areas. The time taken for the procedure and the areas requiring additional flushing are also documented. The procedure is performed as normal to answer the clinical questions posed.

What are the possible benefits and risks of participating?
There will be real immediate benefits from being involved in the test, other than the potential to have a more efficient procedure if the preparation improves visibility. There are no expected risks, the gastroscopy is performed as normal. Both medications have been used for decades and large trials have demonstrated no clinical side effects from their use in low oral doses.

Where is the study run from?
University Hospital Southampton.

When is study starting and how long is it expected to run for?
The study ran from April to August 2011.

Who is funding the study?
There were minimal costs associated with this study and it was self-funded by the investigators within the department.

Who is the main contact?
Dr James Neale

Contact information

Type(s)
Scientific

Contact name
Dr Praful Patel

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/H0504/82

Study information

Scientific Title
Pre-medication with N-acetylcysteine and simethicone improves mucosal visualisation during gastroscopy: a randomised, controlled, endoscopist-blinded study.

Study objectives
We hypothesise that drinking a solution containing n-acetylcysteine (NAC) and simethicone prior to gastroscopy improves endoscopic mucosal visualisation during the procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Southampton B, 19 January 2011, ref: 10/H0504/82

Study design
Randomised controlled endoscopist blinded single centre study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Gastrointestinal endoscopy

Interventions
Patients attend for gastroscopy having already undergone standard preparation at home (6 hours clear fluids only, 2 hours nil by mouth [NBM]).

On entering the study they were randomised (number tables) into 3 groups:
1. Control - no further intervention
2. Water - 100ml sterile water 15-20 minutes prior to gastroscopy
3. Solutiuon - 100ml sterile water + 3ml NAC + 2.5ml simethicone 15-20 minutes prior to gastroscopy

They will have a standard diagnostic gastroscopy performed by endoscopist blinded to this. During procedure all stubborn mucus that cannot be suctioned will be washed with water. The amount of water required, the area of the gastrointenstinal (GI) tract it is used and the time taken for the procedure will be recorded by nursing staff in the room.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
N-acetylcysteine, simethicone

Primary outcome measure
Amount of water required to clear stubborn mucus

Secondary outcome measures
1. Area of GI tract
2. Time taken for procedure

Overall study start date
01/04/2011

Completion date
01/08/2011

Eligibility

Key inclusion criteria
All adult patients attending for clinically required diagnostic gastroscopy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
75

Key exclusion criteria
1. Patients with previous allergic reactions to N-acetylcysteine or simethicone
2. Patients under the age of 18 years old
3. Patients who lack capacity to consent
4. Those patients not medically fit for endoscopy
5. Those patients where it is deemed unsafe to swallow liquids

Date of first enrolment
01/04/2011

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Luminal Gastroenterology
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust (UK)

Sponsor details
Southampton General Hospital
Tremona Road
Southampton
England
United Kingdom
SO16 6YD

Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Southampton NHS Foundation 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results:	01/07/2013		Yes	No