

Drinking a solution prior to gastroscopy improves the view

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

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
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Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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. Solution - 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 gastrointestinal (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(s)

Amount of water required to clear stubborn mucus

Key secondary outcome(s)

1. Area of GI tract
2. Time taken for procedure

Completion date

01/08/2011

Eligibility**Key inclusion criteria**

All adult patients attending for clinically required diagnostic gastroscopy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Department of Luminal Gastroenterology

Southampton

United Kingdom

SO16 6YD

Sponsor information**Organisation**

University Hospital Southampton NHS Foundation Trust (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

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