

Innovative gel aid for administering tablets to stroke and other dysphagic patients

Submission date 23/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/04/2020	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Dysphagia is the medical term for when a patient is having swallowing problems. It can be caused by a number of medical conditions including stroke, dementia and cancers of the mouth or throat. Dysphagia can cause food, drink or medicines to go down the wrong way and so into the lungs. This, in turn, can cause irritation to the lung and, in some cases, a severe lung infection or pneumonia. Water is often taken with medicines to make them easier to swallow. If patients have dysphagia, then both the water and the medicine can end up in the lung, which may lead to infection. We have made a gel that tablets can be placed in that make it easier for them to swallow. This means that patients don't have to drink water when taking the tablet. The gel coats the tablet so it can't be tasted and makes it bigger; this makes it easier to move around the mouth and might help people with dysphagia to swallow it. The gel has been designed to not affect how much of a drug is absorbed once it is in the body. This is important, because if the gel reduces the amount of drug available to be body, it won't be so good at treating a medical condition or disease. In this study, we are looking at whether the gel affects how much of an aspirin tablet is absorbed in the body.

Who can participate?

Healthy men aged between 18 and 35.

What does the study involve?

Participants are randomly allocated to one of two groups. They are asked to make two visits to a clinical trials unit based in a local hospital. On their first visit, participants in group 1 are given a 300mg tablet of aspirin in our gel to swallow. Those in group 2 are given a 300mg tablet of aspirin to swallow with water. On the second visit, this is swapped around, so that those people in group 2 are given the aspirin in the gel and group 1 asked to swallow the tablet with water. At each visit we take a number of blood samples from each participant, at set time points, for 2 hours after they have swallowed the tablets to see how much aspirin has been absorbed into the blood. Platelets are small cells in the blood that stick together to make a blood clot, to close a wound for example. Aspirin reduces the stickiness of these platelets and it's this stickiness of the blood that we are measuring.

What are the possible benefits and risks of participating?

There are no health benefits for the volunteers taking part, but they are paid as a thank you for their help. The results will help us to decide whether using our gel to aid swallowing is a good idea or not. If it is found not to affect the bodys absorption of aspirin, then we will test it in patients to see how acceptable it is in practice. In theory, the gel could be used to help patients to swallow their medicines in the future.

Where is the study run from?

Norfolk and Norwich University Hospital (UK)

When is the study starting and how long is it expected to run for?

July 2014 to October 2020

Who is funding the study?

Medical Research Council (UK)

Who are the main contacts?

Vivienne Maskrey

v.maskrey@uea.ac.uk

Annie Blyth

a.blyth@uea.ac.uk

Contact information

Type(s)

Scientific

Contact name

Ms Annie Blyth

Contact details

Norwich Medical School, Faculty of Medicine and Health Sciences

University of East Anglia

Norwich Research Park

Norwich

United Kingdom

NR4 7TJ

+44 (0)1603 593308

a.blyth@uea.ac.uk

Additional identifiers

Protocol serial number

16803

Study information

Scientific Title

Innovative gel aid for administering tablets to stroke and other dysphagic patients: bioequivalence study to determine the effect of a gel swallowing aid on the release of aspirin in healthy volunteers (study 2)

Study objectives

A new formulation, containing ingredients all commonly used in food, has been developed as a gel to aid tablet administration in patients with swallowing difficulties (dysphagia). The working name for this gel is SMART Swallowing Aid. The study hopes to establish, using healthy volunteers, whether the gel affects the absorption of drug from the incorporated tablet in any way. Twelve volunteers will be recruited from the University of East Anglia and the Norfolk and Norwich University Hospital to swallow a tablet (300 mg aspirin uncoated) encapsulated within the gel, and also the tablet without the gel. The volunteers will be asked to provide blood samples at time points along the absorption process to determine the blood serum concentration of aspirin metabolites. The effect on platelets will also be determined. The study will last a total of 6 hours (3 hours on two separate occasions) for each volunteer. The gels will be prepared at least 24 hours in advance in the hospital pharmacy and stored at room temperature.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Research and Ethics Committee (MREC), 02/06/2014, ref. 14/YH/0176

Study design

Randomised; Interventional; Design type: Not specified, Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Gastroenterology; Subtopic: Gastroenterology; Disease: All Gastroenterology

Interventions

Study Visit 1: Participants will be randomised to either:

1. Swallow an aspirin with the SMART Swallowing Aid
2. Swallow an aspirin with water

Study Visit 2: Crossover treatment - those who swallowed aspirin with the SMART Swallowing Aid aid will swallow with water and vice versa

Study entry: single randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Bioequivalence of aspirin with and without SMART Swallowing Aid; primary outcome measures: platelet function and salicylate assay

The primary outcome, of aspirin blood concentration, is measured in the blood samples which will be taken at time zero then 20, 40, 60, 90 and 120 minutes after the aspirin has been swallowed.

Key secondary outcome(s)

The secondary outcome aims to determine if the gel is easy and comfortable to swallow in comparison with the tablet administered with water. This is measured by a brief questionnaire which is completed after the aspirin has been swallowed.

Completion date

31/10/2020

Eligibility

Key inclusion criteria

1. Healthy
2. Male
3. Age 18 to 35 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

Total final enrolment

881

Key exclusion criteria

1. Participants who are studying at the UEA School of Pharmacy or School of Medicine
2. Participants who dont eat or are allergic to gelatin, HPMC, citric acid or potassium sorbate
3. Participants who are lactose intolerant or suffer with celiac disease
4. Patients who suffer from dysphagia or have difficulty swallowing
5. Participants who are allergic to aspirin or any other NSAID
6. Participants with hypersensitivity to aspirin i.e. attacks of asthma, angioedema, urticaria or

rhinitis precipitated by aspirin or any other NSAID

7. Participants who have active peptic ulceration

8. Participants who have haemophilia or other bleeding disorders

9. Participants taking aspirin regularly or who have taken aspirin in the last 7 days

10. Participants who are taking other medications, particularly those containing salicylates

11. Patients with parallel participation in another research study

12. Any person related to or living with any member of the study team

13. Any person with language difficulties

Date of first enrolment

23/07/2014

Date of final enrolment

30/09/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Medicine

Norwich

United Kingdom

NR4 7TJ

Sponsor information

Organisation

Norfolk and Norwich University Hospital NHS Trust (UK)

ROR

<https://ror.org/01wspv808>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK), Grant Codes: G0902184/1

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
HRA research summary			28/06/2023	No	No