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

Submission date
23/07/2014

Recruitment status
No longer recruiting

Registration date
12/08/2014

Overall study status
Completed

Last Edited
06/04/2020

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 dont have to drink water when taking the tablet. The gel coats the tablet so it cant 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 wont 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 its 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
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Contact information

Type(s)
Scientific

Contact name
Ms Annie Blyth

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the following contact details below to request a patient information sheet: Annie Blyth, Study Coordinator, a.blyth@uea.ac.uk; 01603 593308 or Viv Maskrey, Study Coordinator, v.maskrey@uea.ac.uk; 01603 593966

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 measure
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.

Secondary outcome measures
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.

Overall study start date
23/07/2014

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. Healthy
2. Male
3. Age 18 to 35 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
880 (Updated 06/04/2020, previously Planned Sample Size: 12; UK Sample Size: 12)

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
England

United Kingdom

Study participating centre
School of Medicine
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust (UK)

Sponsor details
Colney Lane
Colney
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United Kingdom
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-
lisa.chalkley@nnuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nnuh.nhs.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date
31/10/2019

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