ISRCTN13972867 https://doi.org/10.1186/ISRCTN13972867

Bioequivalence study of a gel swallowing aid

Submission date 07/11/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/11/2012	**Overall study status** Completed	
Last Edited 05/07/2018	**Condition category** Other	

Plain English summary of protocol

Background and study aims
It is common for many adults and elderly people to have difficulty swallowing tablets or capsules. The School of Pharmacy at the University of East Anglia have developed a jelly-like product designed to enclose tablets making them easier to swallow, without the need for water. The aim of this study is to determine whether the gel swallowing aid has any effect on the absorption of the enclosed drug.

Who can participate?
We are looking to recruit twelve healthy male volunteers, between the ages of 18 and 35 years.

What does the study involve?
Taking part will involve the volunteer attending two morning sessions, at least one week apart. The volunteer will be asked to swallow an aspirin tablet either with the gel swallowing aid or with water, one at each visit. Six blood samples will be taken over the course of two hours. The volunteers will also be asked to complete a short questionnaire at each visit relating to the ease and comfort of the swallow.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the study, however as a thank you for their time, volunteers will receive £50, travel expenses and lunch at each visit. The risks from taking part in the study are very low. The components of the gel swallowing aid are all routinely used in food products. The gel is designed to melt / dissolve quickly when in contact with the body, therefore choking is unlikely. Each volunteer will be given Weetabix and milk before being administered the aspirin tablet in order to protect the stomach against any irritation.

Where is the study run from?
The study will be run in the Clinical Research and Trials Unit at the Norfolk and Norwich University Hospital, Norwich.

When is the study starting and how long is it expected to run for?
January 2013 to March 2013

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Kathryn Andrews
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13464

Study information

Scientific Title
Bioequivalence study of a gel swallowing aid: a randomised study

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 study hopes to establish, using healthy volunteers, whether the gel affects the absorption of drug from the incorporated tablet in any way.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England Cambridge East, 18th June 2012, ref: 12/EE/0097/AM01

Study design
Randomised; Interventional; Design type: Process of Care, 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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Bioequivalence study

Interventions
Each volunteer will be administered an aspirin tablet both with and without the gel swallowing aid on two separate occasions. Six blood samples will be taken over the course of two hours on each occasion. Volunteers will also be asked to complete a short questionnaire relating to the ease and comfort of swallowing the tablet in each scenario.

Twelve volunteers will be recruited from the University of East Anglia and the Norfolk and Norwich University Hospital to swallow a tablet (300mg aspirin) 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. It is envisaged that the study will last a total of 6 hours (3 hours on two separate occasions) for each volunteer. The gels will be prepared up to twenty four hours in advance in the hospital pharmacy and stored at room temperature.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Safety of the gel i.e. to ensure the gel can be administered safely without unacceptable adverse effects.

Secondary outcome measures
To assess the acceptability of the gel swallowing aid using a questionnaire relating to ease and comfort of swallowing the tablet with and without the gel.

Overall study start date
21/01/2013

Completion date
31/03/2013

Eligibility

Key inclusion criteria
Healthy male volunteers aged 18 to 35

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Key exclusion criteria
1. Participants who dont eat or are allergic to gelatin, hydroxypropyl methylcellulose (HPMC), citric acid or potassium sorbate
2. Patients who suffer with dysphagia or difficulty swallowing
3. Participants who are allergic to aspirin or any other Nonsteroidal anti-inflammatory drugs (NSAIDs)
4. Participants with hypersensitivity to aspirin i.e. attacks of asthma, angioedema, urticaria or rhinitis precipitated by aspirin or any other NSAID
5. Participants who have active peptic ulceration.
6. Participants who have haemophilia or other bleeding disorders
7. Participants taking aspirin regularly or who have taken in the last 7 days
8. Participants who are taking other medications, particularly those containing salicylates
9. Patients with parallel participation in another research study
10. Any person related to or living with any member of the study team
11. Any person with language difficulties

Date of first enrolment
21/01/2013

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust (UK)

Sponsor details
Colney Lane
Colney
Norwich
England
United Kingdom
NR4 7UY

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)

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

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