

# Bioequivalence study of a gel swallowing aid

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<b>Registration date</b> 08/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/07/2018	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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.

**Completion date**

31/03/2013

**Eligibility****Key inclusion criteria**

Healthy male volunteers aged 18 to 35

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Male

**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**

United Kingdom

England

**Study participating centre**

Colney Lane

Norwich

United Kingdom

NR4 7UY

**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)

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No