

# An investigation into the influence of intestinal transit rate on the metabolism of dietary sulphate

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/11/2011	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Stephen Lewis

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0544093560 - PROJ 30/10/2000

# Study information

## Scientific Title

### Study objectives

Influence of intestinal transit on sulphate metabolism.

Hydrogen sulphide (H<sub>2</sub>S) can be toxic to the colon. The principle source of H<sub>2</sub>S in the colon is from the conversion of sulphate to sulfide by bacteria. Other sources of H<sub>2</sub>S production include the fermentation of proteins of animal and plant origin. The majority of dietary sulphate is absorbed in the small intestine with relatively small amounts entering the colon. Intestinal transit speed is known to influence the absorption and breakdown of many dietary substances. In particular intestinal transit speed alters the colonic bacterial flora and fermentation of food. The purpose of this study is to look at the influence of intestinal transit time on the metabolism of sulphate as no data exist. If transit is an influence in sulphate metabolism, then many of the findings linking high concentrations of faecal H<sub>2</sub>S to diseases such as ulcerative colitis could be explained. A brief clinical and drug history would be taken.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

GP practice

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Dietary sulphate metabolism

### Interventions

During the protocol volunteers will take (once a day) either:

1. Senna (a laxative)
2. Loperamide (slows down the colon)
3. Placebo tablet

Volunteers will be asked to take a special diet designed to be low in sulphate. Dr Lewis will be in close contact during the study period to answer any queries and ensure that the senna or loperamide are having the desired effect. In addition they will take tablets containing sulphate. Intestinal transit speed will be measured by two methods. Two stool samples will be collected and a urine sample. After completing the protocol volunteers will have a 2-week washout period repeating the protocol but taking a different transit altering tablet. The volunteers will complete all three protocols.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Senna, loperamide

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

10/01/2001

**Completion date**

10/01/2004

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

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

12 volunteers

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

10/01/2001

**Date of final enrolment**

10/01/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Box No 201A**

Cambridge

United Kingdom

CB2 2QQ

## Sponsor information

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## Funder(s)

**Funder type**

Government

## Funder Name

Cambridge Consortium - Addenbrooke's (UK)

## 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?
<a href="#">Results article</a>	results	01/03/2007		Yes	No