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

Submission date	Recruitment status
12/09/2003	No longer recruiting
Registration date	**Overall study status**
12/09/2003	Completed
Last Edited	**Condition category**
15/11/2011	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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 (H2S) can be toxic to the colon. The principle source of H2S in the colon is from the conversion of sulphate to sulfide by bacteria. Other sources of H2S 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 H2S 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?
Results article	results	01/03/2007		Yes	No