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The effect of increased red meat consumption on the formation of N-nitroso compounds in ileostomists

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 30/05/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544112304

Study information

Scientific Title

Study objectives
What is the total N-nitroso compound content of the residue leaving the ileum following consumption of high and low red meat diets?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled crossover group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Surgery: Ileostomy

Interventions
This is a randomised crossover study consisting of three dietary periods. 12 Non-smoking male or female free-living ileostomists will be recruited by advertisement in the newsletter/website of the Ileostomy Association. The study will last for 6 days, during which time volunteers will live at the volunteer suite at the MRC Dunn Human Nutrition Unit. The volunteers will recieve all three dietary interventions in a randomly assigned order.
1. 1x2 day high red meat diet (240 g red meat/day)
2. 1x2 day low red meat diet (60 g red meat/day)
3. 1x2 day no red meat control diet

The diets will contain measured amounts of other types of food, for example bread and vegetables, to provide all the nutrients required.

Each volunteer will be required to collect all ileal effluent produced for determination of apparent total N-nitroso compound, N-proline and N-nitroso myoglobin content. Liquid chromatography/Mass spectrometry (LC/MS) will also be used in an attempt to characterise the N-nitroso compounds further. Genotoxicity tests will be carried out on the effluent.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/05/2002

Completion date
16/05/2005

Eligibility

Key inclusion criteria
12 Subjects in the age range of 20-85 years.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
17/05/2002

Date of final enrolment
16/05/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Dunn Human Nutrition Unit
Cambridge
United Kingdom
CB2 2XY

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
Other

Funder Name
Cambridge Consortium - Addenbrookes (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