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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
16/05/2005

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrookes (UK)

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?
Results article	results	01/03/2007		Yes	No