

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
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/05/2012	Condition category Surgery	☐ Individual participant data

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

Primary study design

Interventional

Study design

Randomised controlled crossover group trial

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 receive 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