The effect of red meat consumption on the formation of N-nitroso compounds, a group of compounds which may be harmful to humans, in relation to colorectal cancer

Recruitment status	Prospectively registered
15/11/2010 No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Cancer	Record updated in last year
	No longer recruiting Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Theo de Kok

Contact details

Universiteitssingel 50 Maastricht Netherlands 6229 ER +31 (0)43 3881091 t.dekok@grat.unimaas.nl

Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

A non-randomised controlled trial to compare the effect of colon inflammation in combination with a 7-day 300 grams/day red meat diet on the endogenous formation of potentially carcinogenic N-nitroso compounds in the colon of inflammatory bowel disease patients versus non-inflamed irritable bowel syndrome patients, in relation to colorectal cancer risk

Study objectives

We hypothesise that both colon inflammation and a diet high in red meat increase the endogenous formation of potentially carcinogenic N-nitroso compounds in the human colon and that these compounds increase the colorectal cancer risk, which could (partially) explain the increased colorectal cancer risk that is associated with inflammatory bowel disease and diets high in red meat.

Inflammatory bowel disease is characterised by a chronic inflammation within the gastrointestinal tract, which, in case of ulcerative colitis, is present in the colon and rectum.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Ethical Approval Committee (METC) Atrium Orbis Zuyd in Heerlen approved on the 23rd January 2007 (ref: METC 04-P-04A; reg no: NL13359.096.06)

Study design

Non-randomised interventional multicentre study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Inflammatory bowel disease; colorectal cancer risk

Interventions

Both inflammatory bowel disease patients and irritable bowel syndrome control patients participate in a 7-day dietary intervention in which 300 grams of red meat products (steak, etc) are consumed daily. Collection of colon biopsies by endoscopic examination, blood collection by venipuncture, and urine and faecal matter collection takes place at the beginning and the end of the dietary intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

- 1. Whole genome gene expression modifications by microarray analysis (4x44K Agilent platform)
- 2. Apparent total nitroso compounds in faecal matter by thermal energy analysis
- 3. Faecal water genotoxicity (30 minute exposure to 10% faecal water) by comet assay analysis in the adenocarcinoma cell line Caco-2

All outcomes are measured at baseline and post intervention.

Key secondary outcome(s))

- 1. Calprotectin levels in faecal matter as a measure of inflammation
- 2. Analysis of food frequency questionnaires recorded during intervention period
- 3. Possible determination of N-nitroso compound levels by thermal energy analysis in urine and blood

All outcomes are measured at baseline and post intervention.

Completion date

31/12/2010

Eligibility

Key inclusion criteria

- 1. Inflammatory bowel disease patients with an active form of ulcerative colitis with a moderate exacerbation of their disease and in whom the inflammation does not go beyond the flexure lienalis
- 2. Irritable bowel syndrome control patients with endoscopically proven absence of inflammation and adenomas
- 3. Participants of any age (above 18 years) and either sex are included

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Inflammatory bowel disease patients with severe inflammation, including Crohn's disease and pancolitis
- 2. Irritable bowel syndrome control patients with medical complaints and/or use of antiinflammatory medication

Date of first enrolment

Date of final enrolment 31/12/2010

Locations

Countries of recruitment

Netherlands

Study participating centre Universiteitssingel 50 Maastricht Netherlands 6229 ER

Sponsor information

Organisation

Maastricht University (Netherlands)

ROR

https://ror.org/02jz4aj89

Funder(s)

Funder type

University/education

Funder Name

Maastricht University (Netherlands) - internal funding

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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes