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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

Submission date 15/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/12/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/12/2010	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
23/01/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 participants in total, of whom 40 inflammatory bowel disease (ulcerative colitis) patients and 40 control patients with irritable bowel syndrome.

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 anti-inflammatory medication

Date of first enrolment
23/01/2007

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)

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

Sponsor type
University/education

Website
http://www.maastrichtuniversity.nl/

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
University/education

Funder Name
Maastricht University (Netherlands) - internal funding

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