

# 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

<b>Submission date</b> 15/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 14/12/2010	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

## 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 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)

**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