

Protein acetylation as a diet-modifiable biomarker of colorectal cancer risk

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|--|---|---|
| Submission date 08/04/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 04/08/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 11/01/2018 | Condition category Cancer | <input type="checkbox"/> 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
N12017

Study information

Scientific Title
Protein acetylation as a diet-modifiable biomarker of colorectal cancer risk: an interventional single-centre cross-section trial

Acronym

The FACT study

Study objectives

We hypothesise that the reduced risk of colorectal cancer through increased fibre intake is mediated in part through changes in global protein acetylation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North Sheffield Ethics Committee gave approval on the 11th October 2006 (ref: 06/Q2308/93)

Study design

Interventional single-centre non-randomised non-controlled cross-section trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colorectal cancer/bowel health

Interventions

Volunteers with a low habitual consumption of non-starch polysaccharides (NSP) and resistant starch (RS) will be recruited to an 8-week high fibre intervention trial. Volunteers will be provided with a range of high-fibre food options, with the goal of reaching 20 g per day fibre intake.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Altered faecal short chain fatty acid (SCFA) production.

In the cross-sectional arm there is a single sampling timepoint and all primary and secondary measures are made at this point. For the intervention arm sampling is performed at baseline and after 8 weeks of intervention.

Key secondary outcome(s)

1. Altered bowel crypt cytokinetics (proliferation, apoptosis and apoptosis regulators)
2. Identification of candidate biomarker acetylations

In the cross-sectional arm there is a single sampling timepoint and all primary and secondary measures are made at this point. For the intervention arm sampling is performed at baseline and after 8 weeks of intervention.

Completion date

30/09/2009

Eligibility

Key inclusion criteria

1. Aged 40 years and above, either sex for interventional arm and male only for cross-sectional arm
2. Adenoma, normal or cancer colon (30 of each group)
3. Body mass index (BMI) between 20 and 29 kg/m²

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe medical or psychiatric illness
2. Unable to understand or communicate effectively

Date of first enrolment

01/07/2006

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Human Nutrition Unit

Sheffield

United Kingdom

S10 2RX

Sponsor information

Organisation

University of Sheffield (UK)

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Government

Funder Name

Food Standards Agency (UK) (ref: N12017)

Alternative Name(s)

The Food Standards Agency, FSA

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Biotechnology and Biological Sciences Research Council (BBSRC) (UK) (ref: BB/D 004187/1)

Alternative Name(s)

UKRI - Biotechnology And Biological Sciences Research Council, Agricultural and Food Research Council, Biotechnology & Biological Sciences Research Council, BBSRC, BBSRC UK, AFRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Results article | results | 17/04/2015 | | Yes | No |
| Protocol article | protocol | 18/09/2009 | | Yes | No |