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

Submission date 08/04/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 04/08/2009	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 11/01/2018	**Condition category** Cancer	[_] 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)

Primary study design
Interventional

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

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/m^2

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