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The influence of methylenetetrahydrofolate reductase C677T genotype and folate status on deoxyribonucleic acid methylation and uracil misincorporation in the colon of healthy volunteers

Submission date 04/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/10/2006	**Overall study status** Completed	
Last Edited 16/01/2020	**Condition category** Cancer	

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
JQADGAR

Study information

Scientific Title
The influence of methylenetetrahydrofolate reductase C677T genotype and folate status on deoxyribonucleic acid methylation and uracil misincorporation in the colon of healthy volunteers

Acronym
FolGene

Study objectives
Increasing folate status and the MethyleneTetraHydroFolate Reductase (MTHFR) C677T genotype influence intermediary biomarkers of preclinical neoplasia (DeoxyriboNucleic Acid [DNA] methylation and uracil misincorporation) in human colonic epithelium.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's College Hospital Research Ethics Committee, 13/07/2006, ref: 06/Q0703/29

Primary study design
Interventional

Study design
Randomised, double blind, placebo controlled, parallel study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
400 µg per day folic acid or placebo for three months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Folic acid

Primary outcome(s)
Changes in genomic and gene specific DNA methylation and uracil misincorporation.

Key secondary outcome(s)
Changes in blood and tissue folate and plasma homocysteine.

Completion date
11/09/2009

Eligibility

Key inclusion criteria
No lesions detected on full colonoscopy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Colorectal polyps or cancer discovered at present colonoscopy
2. Current or previous diagnosis of cancer, or a strong family history of colorectal cancer or adenomatous polyposis coli
3. Inflammatory bowel disease
4. Current or past history of gluten-sensitive enteropathy
5. Clinical and/or laboratory evidence of intestinal malabsorption
6. Significant renal or liver disease
7. Pregnancy
8. Epilepsy
9. Alcoholism
10. Pernicious anaemia
11. Serum vitamin B12 levels less than 180 ng/l and the use of medication known to antagonise the metabolism of folate

Date of first enrolment
11/09/2006

Date of final enrolment
11/09/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE1 9NH

Sponsor information

Organisation
King's College London Nutritional Sciences Research Division

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Sciences Research Council (BBSRC) (reference number: BB /D523178/1)

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	01/12/2013		Yes	No