

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
Registration date 06/10/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/01/2020	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Maria Pufulete

Contact details
King's College London
Franklin-Wilkins Building
150 Stamford Street
Waterloo
London
United Kingdom
SE1 9NH
+44 (0)20 7848 4270
maria.pufulete@kcl.ac.uk

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

Study design

Randomised, double blind, placebo controlled, parallel study

Primary study design

Interventional

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