

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

<b>Submission date</b> 04/08/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/01/2020	<b>Condition category</b> 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**  
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?
<a href="#">Results article</a>	results	01/12/2013		Yes	No