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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Maria Pufulete

#### Contact details

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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, BBSRC UK, Biotechnology and Biological Sciences Research Council (BBSRC), BBSRC

## **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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleo1/12/2013YesNoParticipant information sheetParticipant information sheet11/11/202511/11/2025NoYes