

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/10/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/01/2020	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Changes in genomic and gene specific DNA methylation and uracil misincorporation.

Secondary outcome measures

Changes in blood and tissue folate and plasma homocysteine.

Overall study start date

11/09/2006

Completion date

11/09/2009

Eligibility**Key inclusion criteria**

No lesions detected on full colonoscopy

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

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

England

United Kingdom

Study participating centre

King's College London

London

United Kingdom

SE1 9NH

Sponsor information

Organisation

King's College London Nutritional Sciences Research Division

Sponsor details

Hodgkin Building

Guy's Campus

London

England

United Kingdom

SE1 1UL

Sponsor type

University/education

Website

<http://www.kcl.ac.uk>

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, BBSRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No