

Synthetic folic acid intakes and status in children living in Ireland exposed to voluntary fortification.

Submission date 14/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/10/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Children being exposed to folic acid has become a cause of concern, particularly as it may have adverse events (i.e. damage to health) in the future. There is not yet any published data on the levels of unmetabolised folic acid (UFA) in the circulation of children living in Ireland. The aim of this study is to explore the levels of fasting UFA in the circulation of children living in Ireland exposed to the voluntary folic acid fortification regime in place there.

Who can participate?

Healthy children attending for routine minor surgery at Our Lady's Hospital, Crumlin, Dublin (Ireland).

What does the study involve?

Participants are asked to provide a fasting 3ml blood sample taken when under a general anaesthetic. The samples are then analysed for plasma and red cell folate and UFA levels. A short dietary questionnaire capturing recent and habitual intake of folic acid both as supplements, and as fortified foods is also completed face to face with parents.

What are the possible benefits and risks of participating?

This study will help with understanding the intakes of folic acid from fortified foods and supplements in children in Ireland and how this intakes affects their folic acid levels in their blood. Risks are not anticipated.

Where is the study run from?

Our Lady's Children's Hospital, Dublin (Ireland)

When is the study starting and how long is it expected to run for?

September 2013 to February 2014

Who is funding the study?

Centre for Preventive Medicine, Dublin City University (Ireland)

Who is the main contact?
Dr Mary Rose Sweeney

Contact information

Type(s)
Scientific

Contact name
Dr Mary Rose Sweeney

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Additional identifiers

Protocol serial number
REC reference GEN/280/12

Study information

Scientific Title
Synthetic folic acid intakes and status in children living in Ireland exposed to voluntary fortification: an observational study

Study objectives
Aims: To explore the levels of fasting UFA in the circulation of children living in Ireland exposed to the voluntary folic acid fortification regime in place there.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee at Dublin City University and the Ethics Committee at Our Lady's Children's Hospital, Crumlin, REC ref: GEN/280/12

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied

Healthy children attending for routine minor surgery

Interventions

Healthy children attending for routine minor surgery at Our Lady's Hospital, Crumlin, Dublin were recruited to provide a fasting 3ml blood sample taken while administering a general anaesthetic. The samples were analysed for plasma and red cell folate and UFA levels. A short dietary questionnaire capturing recent and habitual intake of folic acid both as supplements, and as fortified foods was completed face to face with parents.

Intervention Type

Supplement

Primary outcome(s)

Unmetabolised folic acid levels, as measured by HPLC.

Key secondary outcome(s)

Plasma and red cell folate levels, with the analysis conducted in batch assay by L. casei microbiological assay.

Completion date

01/02/2014

Eligibility**Key inclusion criteria**

Children admitted for routine minor surgery under general anesthetic

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Unwell children presenting with any condition potentially affecting folate absorption such as a gastrointestinal condition, metabolic condition, shock, burns or post trauma

Date of first enrolment

01/09/2013

Date of final enrolment

01/02/2014

Locations

Countries of recruitment

Ireland

Study participating centre

Our Lady's Children's Hospital

Crumlin

Dublin

Ireland

D8

Sponsor information

Organisation

Dublin City University

ROR

<https://ror.org/04a1a1e81>

Funder(s)

Funder type

University/education

Funder Name

Centre for Preventive Medicine, Dublin City University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No

