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

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

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)

Contact information

Type(s)

Scientific

Contact name

Dr Mary Rose Sweeney

Contact details

School of Nursing and Human Sciences Dublin City University Glasnevin Dublin Ireland D9

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

Unmetabolised folic acid levels, as measured by HPLC.

Secondary outcome measures

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

Overall study start date

01/09/2013

Completion date

01/02/2014

Eligibility

Key inclusion criteria

Children admitted for routine minor surgery under general anesthetic

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

60

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

Sponsor details

Glasnevin Dublin Ireland D9

Sponsor type

University/education

ROR

https://ror.org/04a1a1e81

Funder(s)

Funder type

University/education

Funder Name

Centre for Preventive Medicine, Dublin City University

Results and Publications

Publication and dissemination plan

The paper is being submitted to the American Journal of Clinical Nutrition

Intention to publish date

31/08/2015

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