ISRCTN90038765 https://doi.org/10.1186/ISRCTN90038765

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

Registration date
07/10/2015

Overall study status
Completed

Last Edited
15/01/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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