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Can developmental programming of adiposity and insulin resistance in rural Indian children be reversed during adolescent growth by vitamin B12 supplementation? A pilot study

Submission date
04/09/2007

Registration date
07/09/2007

Last Edited
15/10/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.kemdiabetes.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
079877/Z/06/Z

Study information

Scientific Title

Study objectives
Primary hypothesis:
To test the hypothesis (H0) that, in children and their parents from the Pune Maternal Nutrition Study (PMNS), daily supplementation with either 2 µg or 10 µg of vitamin B12, with or without folic acid (at 4 months and 1 year), has no effect on serum levels of vitamin B12, total Homocysteine (tHcy), folate and Methylmalonic Acid (MMA).

Secondary hypotheses:
1. To test the hypothesis that in children from the PMNS, daily supplementation with either 2 µg or 10 µg of vitamin B12, with or without folic acid, for 12 months has no effect on body composition, insulin resistance (Homeostasis Model Assessment [HOMA]) or neuro-cognitive performance
2. To test the hypothesis that in the parents from the PMNS, daily supplementation with either 2 µg or 10 µg of vitamin B12, with or without folic acid, for 12 months has no effect on body composition and insulin resistance

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the King Edward Memorial Hospital And Research Centre Ethics Committee on the 11th April 2006 (ref: KEMHRC/VSP/Dir Off/EC/065; Project No. 067).

Study design
Single-centre, interventional, randomised, double blind, 2 x 3 factorial study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Micronutrient deficiency in Developmental Origins of Health and Disease (DOHaD)

Interventions
Each participant will be given one of the following six medications, to be taken orally, one capsule per day for a period of 12 months:
1. Folic acid, 0 µg and vitamin B12, 0 µg (placebo)
2. Folic acid, 0 µg and vitamin B12, 2 µg
3. Folic acid, 0 µg and vitamin B12, 10 µg
4. Folic acid, 200 µg and vitamin B12, 0 µg
5. Folic acid, 200 µg and vitamin B12, 2 µg
6. Folic acid, 200 µg and vitamin B12, 10 µg

Secondary sponsor for this trial:
MRC, Epidemiology Resource Centre
Southampton General Hospital
Southampton, S016 6YD
United Kingdom
Tel: +44 (0)2380 777624
http://www.mrc.soton.ac.uk

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
B12 and folic acid supplementation

Primary outcome measure
Serum levels of vitamin B12, folate, tHcy, and MMA, measured at the end of four months and twelve months of supplementation.

Secondary outcome measures
1. Haemogram
2. Blood glucose
3. Lipid profile
4. Serum creatinine
5. Insulin levels
6. Body composition (anthropometry, Dual Energy X-ray Absorptiometry [DEXA])*
7. Blood pressure
8. Grip-strength*
9. Neuro-cognitive performance*
10. Arterial elasticity*
11. Food Frequency Questionnaire (FFQ)*

(* These will be measured only in children). All secondary outcomes to be measured at the end of 12 months of supplementation.

Overall study start date
01/04/2007

Completion date
31/03/2008

Eligibility

Key inclusion criteria
Parents and children belonging to a subset of the Pune Maternal Nutrition Study cohort consenting for participation.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
110 families (330 individuals)

Key exclusion criteria
1. Refusal to participate
2. Not available to complete the study for 12 months
3. Haemoglobin below lower limit of normal for sex and age, requiring treatment with iron and folic acid, vitamin B12, or both
4. Need to take drugs known to impair the absorption or utilisation of folic acid and vitamin B12, e.g., some antiepileptics
5. Women of child bearing age will be excluded if becoming pregnant
6. Individuals who are taking folic acid and/or vitamin B12 supplements since ten or more days

Date of first enrolment
01/04/2007

Date of final enrolment
31/03/2008

Locations

Countries of recruitment
India

Study participating centre
Diabetes Unit, 6th Floor
Pune

India
411011

Sponsor information

Organisation
King Edward Memorial (KEM) Hospital and Research Centre (India)

Sponsor details
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Pune
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diabetes@vsnl.com

Sponsor type
Hospital/treatment centre

Website
http://www.kemdiabetes.com

ROR
https://ror.org/03vcw1x21

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (ref: 079877)

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