

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/10/2008	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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Contact details

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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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+91 (0)20 2611 1958
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