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The effect of a micronutrient rich food on Indian women's health and nutrient status

Submission date	Recruitment status	[X] Prospectively registered
16/06/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/07/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/10/2014	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial investigating the change in micronutrient status of Indian women as a result of consuming a micronutrient rich food

Study objectives
Daily consumption of a fruit based supplement over a three-month period will produce an improvement in the nutrient status and in functional health indicators measured in young Indian women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee, Deaprtment of Pharmacology, Grant Medical College & Sir JJ Group of Hospitals, Mumbai, India, 07/10/2009, ref: No.IEC/Pharm/482/09

Study design
Interventional single-centre randomised non-blinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Micronutrient deficiencies, functional health

Interventions
The intervention is an experimental food consumed six days per week. The experimental food is a micronutrient rich snack weighing approx 65 g, (energy value: about 180 kcal) containing 20 g green leafy vegetables (e.g. spinach, coriander, amaranth), 10 g fruit (figs, dates, raisins) and 12 g dried milk powder. The control food contains foods of low micronutrient content including potato, tapioca and onion. All snacks contain spices and binding ingredients such as flour and resemble a samosa or patty. There are a variety of recipes in the intervention and control groups to prevent monotony.

Total duration of treatment: 12 weeks; at present no follow-up is planned. Final measurements will be taken at 12 weeks after the start of supplementation.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
1. Serum retinol using high-performance liquid chromatography (HPLC)
2. Plasma vitamin C using HPLC
3. Serum folate and serum vitamin B12 using microbiological assays
4. Serum ferritin using enzyme-linked immunosorbent assay (ELISA) method

Samples taken at 0, 6 and 12 weeks after supplementation starts.

Added 13/10/2014:
5. Plasma and erythrocyte fatty acids, analysed using gas chromatography
6. Erythrocyte antioxidant enzyme SOD, analysed using enzyme-linked immunosorbent assay (ELISA) Cayman's kit
7. Erythrocyte antioxidant enzyme GPx, analysed using colorimeter
8. Plasma malondialdehyde, analysed spectrophometrically

These outcomes were measured at baseline (0 week) and 12 weeks after supplementation started.

Secondary outcome measures
1. Grip strength measured using a hand held dynamometer
2. Body composition by anthropometry
3. Changes in diet as a result of consumption of the snack measured using 3 x 24 hour recalls and a Food Frequency Questionnaire
4. Night blindness measured by questionnaire

Measurements made at 0 and 12 weeks after supplementation starts.

Overall study start date
01/10/2009

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Female
2. Aged 16 - 35 years
3. Living in the Ghatkopar area of Mumbai, India
4. Not pregnant
5. Not lactating
6. Willing to consume the snack food for 3 months

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
160

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2009

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
Medical Research Council - Epidemiology Resource Centre
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Medical Research Council (MRC) (UK) - Epidemiology Resource Centre

Sponsor details
Southampton General Hospital
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Sponsor type
Research council

Website
http://www.mrc.soton.ac.uk

ROR
https://ror.org/052578691

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) - Epidemiology Resource Centre

Funder Name
Centre for the Study of Social Change (India)

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