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Growth and body composition in undernourished children: effect of vitamin B12 supplementation

Submission date	Recruitment status	[ ] Prospectively registered
02/09/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/11/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/11/2010	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

0938

Study information

Scientific Title
Growth and body composition in acute severe malnutrition (SAM) in Indian children: effect of vitamin B12 supplementation in a double-blind randomised controlled pilot study

Acronym
GROW SAM

Study objectives
Developing countries like India undergoing rapid industrialisation and transition are facing a dual burden of illness viz. undernutrition and overnutrition. Both of these dimensions of malnutrition contribute to morbidity and mortality in children as well as in adults. It is estimated that undernutrition contributes to 50% of the child deaths in the country. The children who survive nutritional insults during early life are at a high risk of developing non-communicable diseases (NCD) like type 2 diabetes, obesity and cardiovascular disease in later life. India is today a capital of diabetes as well as of undernutrition in under-five children.

The theory of 'developmental origins of health and disease' (DOHaD) suggests that obesity, diabetes and related disorders have origins in nutritional rehabilitation of the undernourished young. Undernutrition followed by overnutrition in later life predisposes to NCD. A major concern in India is to treat and rehabilitate undernourished children especially in the rural population.

We plan to study growth and body composition of undernourished children in the age group of 6 months to 36 months, in Akola district of State of Maharashtra. We plan to study the effect of vitamin B12 supplementation on lean mass deposition during recovery from malnutrition in these children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
KEM Hospital Research Centre's Ethics Committee approved on the 23rd July 2009 (ref: KEMHRC /VSP/Dir Off/EC/1005)

Study design
Double-blind randomised controlled pilot study

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
Acute severe malnutrition (SAM)

Interventions
Oral supplementation with multiple micronutrients, with and without vitamin B12. 10 g sachets of multiple micronutrients were prepared (as per IOM RDA for 3 year olds); patients were given 1 sachet/day orally (provided in color coded sachets). Total duration of treatment was 6 months.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
B12 supplementation

Primary outcome measure
1. Total body water, measured by D2O dilution method, measured at baseline and visit 5
2. Bio-impedance analysis, measured at baseline, visit 3 and visit 5

Secondary outcome measures
1. Anthropometry, measured at baseline and visit 5
2. Blood measurements, measured at baseline and visit 5

Overall study start date
01/07/2010

Completion date
30/06/2011

Eligibility

Key inclusion criteria
Children less than or equal to -3 sd weight for height, as per World Health Organization (WHO) growth standards, aged 6 - 36 months

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
36 Months

Sex
Both

Target number of participants
100

Key exclusion criteria
Children with acute illness or with incapacitating congenital malformation

Date of first enrolment
01/07/2010

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
India

Study participating centre
Diabetes Unit
Pune
India
411 011

Sponsor information

Organisation
King Edward Memorial Hospital and Research Centre (India)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056yyyw24

Funder(s)

Funder type
Research organisation

Funder Name
International Atomic Energy Agency (IAEA) (Austria)

Alternative Name(s)
IAEA

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Austria

Funder Name
King Edward Memorial Hospital and Research Centre (India) - Diabetes Unit

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