

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

<b>Submission date</b> 02/09/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/11/2010	<b>Condition category</b> 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

## 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

## 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**

Diabetes Unit

Rasta Peth

Pune

Maharashtra

India

411011

kemvnr@vsnl.net

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/056yyw24>

**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