

Comparing compliance and efficacy of isocaloric oral supplementation using 1.5 Kcal/mL or 1 Kcal/mL sip feeds in mild to moderate malnutrition in children

Submission date 28/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/05/2011	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

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Comparing compliance and efficacy of isocaloric oral supplementation using 1.5 Kcal/mL or 1 Kcal/mL sip feeds in mild to moderate malnutrition in children: an open label, parallel, randomised controlled trial

Study objectives

Is compliance and efficacy of high calorie supplementation given orally better than standard one in mild to moderate malnourished children?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee Faculty of Medicine of University of Indonesia approved on April 25th 2011 (224/PT02.FK/43/N/2011)

Study design

Open label parallel randomised controlled trial

Primary study design

Intentional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild to moderate malnutrition

Interventions

Ready to drink oral supplementation 600 kcal for 28 days. Study group will receive 2 bottles each 200 mL, 1.5 kcal/mL product. Controlled group will receive 3 bottles each 200 mL 1kcal/mL product.

The randomisation was done by a statistician not included in this study. He then sealed in the envelopes with consecutive number at front page. If a patient enters the study, we pick number accordingly then check the code inside. The code is A or B. The investigator knows what the codes A and B are for but the statistician doesn't. After completion of the study, the statistician will analyse the data and at the end, we all meet to hear the result from him and disclose the code to the statistician.

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Isocaloric oral supplementation

Primary outcome(s)

1. Weight gain: measure body weight every week of intervention
2. Product consumption: measure the remainings in bottle(s)
3. Gastrointestinal complaints: questionnaire and bristol stool chart

Key secondary outcome(s)

Calorie intake from solid food before and after intervention: 24 recall diet before (day 1) and after intervention (day 29)

Completion date

30/06/2011

Eligibility

Key inclusion criteria

1. Boys and girls aged 3-5 years
2. Z-score for weight-for-height is -1 to -3 according to the World Health Organisation (WHO 2006) growth standards
3. Child is used to drinking milk
4. Stable health status (in the opinion of the Health Care Professional)
5. Written informed consent from parents/caretakers

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 years

Upper age limit

5 years

Sex

All

Key exclusion criteria

1. Taking medications which increase appetite (appetite stimulants), such as steroids, cyproheptadine
2. Conditions which need a special diet like major renal and hepatic dysfunction
3. Known cows milk allergy, galactosaemia, major gastrointestinal intolerance (e.g. severe vomiting, severe diarrhoea)
4. Children requiring a fiber-free diet
5. Children with oedema
6. Use of parenteral feeding and/or enteral tube-feeding
7. Investigator's uncertainty about the willingness or ability of the child/caretaker to comply with the protocol requirements
8. Participation in any other study involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

Date of first enrolment

02/05/2011

Date of final enrolment

30/06/2011

Locations

Countries of recruitment

Indonesia

Study participating centre

Departemen Ilmu Kesehatan Anak Fkui

Jakarta

Indonesia

10430

Sponsor information

Organisation

University of Indonesia (Indonesia)

ROR

<https://ror.org/0116zj450>

Funder(s)

Funder type

Industry

Funder Name

Nutricia (Indonesia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration