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	Recruitment status	Prospectively registered
28/04/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/05/2011	Completed	☐ Results
Last Edited	Condition category	Individual participant data
09/05/2011	Nutritional, Metabolic, Endocrine	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Yoga Devaera

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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 efficafy of high calorie supplementation given orally better than standard one in mild to moderate malnurished 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

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

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 measure

- 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

Secondary outcome measures

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

Overall study start date

02/05/2011

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

Age group

Child

Lower age limit

3 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

110

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)

Sponsor details

Deapartment of Child Health Faculty of Medicine

c/o Dr Yoga Devaera Jakarta Indonesia 10430

Sponsor type

University/education

ROR

https://ror.org/0116zj450

Funder(s)

Funder type

Industry

Funder Name

Nutricia (Indonesia)

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