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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

Registration date
09/05/2011

Overall study status
Completed

Last Edited
09/05/2011

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Departemen Ilmu Kesehatan Anak Fkui
Jl Salemba 6
Jakarta
Indonesia
10430

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