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Effects of biscuit supplementation fortified with zinc, glutamine, prebiotics, and dietary fiber on intestinal mucosal rehabilitation in children aged 12-18 months with undernutrition

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
09/01/2018

Overall study status
Completed

Last Edited
08/01/2018

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary
Background and study aims
Malnutrition is still a problem in developing countries such as Indonesia. Undernutrition can cause damage to the mucus in the intestines (intestinal atrophy) causing problems in the intestines including not being able to absorbed nutrients, problems with the pancreas, and lactose intolerance. Intestinal atrophy in malnourished children can be rehabilitated with improving intestinal mucosal thickness in malnourished infants after nutritional rehabilitation. Supplementation of some nutritional components is essential in regenerating the intestinal mucosa. Some components of nutrients that can repair the intestinal mucosa include glutamine, zinc, prebiotics, and dietary fiber. In this research, biscuits will be fortified with glutamine, zinc, probiotics, and dietary fiber as therapy to improve the integrity of intestinal mucosa in children with undernutrition. The aim of this study is to see if the intestinal mucus and nutrition status can be improved with fortified biscuits in children.

Who can participate?
Children aged 12-18 months who are malnourished.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a fortified biscuits twice a day to take as a supplement. Those in the second group receive a placebo (dummy) biscuit twice a day. Participants are followed up with urine tests, and stool tests at three and six months.

What are the possible benefits and risks of participating?
Participants may benefits from receiving biscuits which contains nutrients. The biscuit had been proven to give advantages for better nutritional status. Thus, the Control group will be expected to have increasing nutritional status. Since the Intervention biscuits will be fortified with more zinc, glutamine, inulin, and fibre, writer have the hypothesis that Intervention group will have better increment nutritional status through improvement in intestinal mucosa permeability. Any

costs of this research will not be charged to the participant's parents, thus saving the family's daily expenses for their child's food supplementation. Participants are expected to have better nutritional status leading to better health. Therefore, they will have bigger opportunity to grow as healthy adults and better performance in school. Although it’s rare, there are possible adverse effects of consuming the biscuit/s including bloating, diarrhea, flatulence, and abdominal discomfort.
Where is the study run from?
This study is taking place in neighborhood groups in Posyandus in Palmerah District, West Jakarta (Indonesia).

When is the study starting and how long is it expected to run for?
January 2017 to December 2018

Who is funding the study?
Investigator initiated and funded (Indonesia)

Who is the main contact?
Dr Eva Jeumpa Soelaeman (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17-06-0605

Study information

Scientific Title

Effects of biscuit supplementation fortified with zinc, glutamine, prebiotics, and dietary fiber on intestinal mucosal rehabilitation in children aged 12-18 months with undernutrition: A Study of Integrity of Intestinal Mucosa and Growth

Study hypothesis
1. Improving the integrity of the intestinal mucose is better by administering biscuits fortified with glutamine, zinc, prebiotics and dietary fibers than by giving biscuits without fortification in undernourished children aged 12-18 months, assessed by IFAB, AAT and calprotectin examinations.
2. Improvement in nutrient absorption is better in biscuits fortified with glutamine, zinc, prebiotics and dietary fiber than in those without fortified biscuits in undernourished children aged 12-18 months, assessed by stool steatocrite examination.
3. Improved growth / better nutritional status in the administration of biscuits fortified with glutamine, zinc, prebiotics and dietary fiber than if given biscuits without fortification in children less than 12-18 months of age, assessed by anthropometric examination (body weight and body lenght).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Faculty of Medicine University of Indonesia and Cipto Mangunkusumo Hospital Jakarta, 19/06/2017, ref: 568 / UN2.F1 / ETIK / 2017 and protocol number: 17-06-0605

Study design
Interventional single-centered study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available, because the participants have not been recruited yet

Condition
Malnourishment

Interventions
Interventions are performed by giving biscuits fortified with glutamine, zinc, prebiotics, and dietary fiber to the subjects. The subjects of 68 people are randomly allocated to one of two groups, namely 34 people in the intervention group and 34 control groups. Randomisation is done by block technique 4 (four). Interventions are double-blinded with biscuit packaging, both

fortified and placebo, made in the same form and packaging, differing only in content. In the intervention group, participants receive fortified biscuits as much as two pieces per day as a dietary supplement. Those in the control group receive a placebo biscuit as much as two pieces per day as a dietary supplement.

Intervention Type
Supplement

Primary outcome measure
1. Improvement in intestinal integrity in undernourished children 12-18 months with improvement in markers of bowel integrity through examination of Intestinal Fatty Acid Binding Protein (IFABP), Alpha-1-Antitrypsin (AAT), and Calprotectin in children ages 12-18 months with malnutrition:
1.1. IFABP is measured using “urine” tests, ELISA method, at baseline, 3 months and 6 months
1.2. Calprotectin is measured using “stool” tests, ELISA method, at baseline, 3 and 6 months
1.3. AAT is measured using “stool” tests, ELISA method, at baseline, 3 and 6 months

Secondary outcome measures
1. Improvement in nutrient absorption, marked with improvement in Steatocrite level measured using “stool” tests, ELISA method at baseline, 3 and 6 months
2. Improvement in nutritional status. Nutritional status is based on improvement in Z-Score (WHZ and HAZ), measured at the end of every month during 6 months of intervention. Weight is measured using digital weight scale for children under 2 years old (brand will be confirmed later). Height is measured using manual height scale (brand will be confirmed later). WHZ and HAZ are calculated by Anthropometry Calculator Application published by WHO.

Overall study start date
01/01/2017

Overall study end date
31/12/2018

Eligibility

Participant inclusion criteria
1. Age 12-18 months
2. Malnutrition
3. Parents are willing to sign informed consent after being briefed and informed about the research

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Months

Upper age limit

18 Months

Sex
Both

Target number of participants
Minimum 68 persons

Participant exclusion criteria
Suffering from chronic illness (congenital heart disease, nephrotic syndrome, digestive problems, worms and other chronic diseases).

Recruitment start date
01/02/2018

Recruitment end date
31/05/2018

Locations

Countries of recruitment
Indonesia

Study participating centre
Palmerah district
Palmerah district
West Jakarta
Indonesia
11420

Sponsor information

Organisation
University Indonesia

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Sponsor type

University/education

ROR
https://ror.org/0116zj450

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other