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STUDY PROTOCOL

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Effectivity of Liquid Nutritional Supplementation in Improving Nutritional Status of Hospitalized Malnutrition Patients: A Single-Blind Randomized Controlled Trial

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Title

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Background

Malnutrition is a common problem that is found in hospitalized patients. A study by Allard et al[1] found that in Canada, 45% of hospitalized patients had malnutrition. Another studies in Europe, 20-30% of hospitalized patients also had malnutrition.[2,3] Lim et al4 also conducted a study and found malnutrition in 27-39% subjects who were hospitalized. Malnutrition is a condition which there were unbalanced energy, protein or other nutrition that results in underweight or overweight. Malnutrition in hospitalized patients is due to unfullfiled nutrient intake, malabsorption, nutrient loss due to main disease or increased metabolic demand.[5,6]

Recent studies showed that malnutrition increases morbidity and mortality. Malnutrition also extends hospitalisation duration and recovery time. These will increase hospitalisation cost.[7-9] Therefore, nutrition is an important key in malnutrition treatment. Nutritional supplementation can be given in improving nutritional status. Liquid form is a alternative in supplying nutrition to hospitalized patients since the consistency made it easier to swallow. Nowadays nutritional supplement in liquid form is available from commercial product or hospital product. Therefore, we need a study to know effectivity liquid nutritional supplement from hospital product in malnutrition hospitalized patients.

Objective

General objective

To know the effectivity of liquid nutritional supplementation in malnutrition hospitalized patients

Specific objectives

1. To know the change of Body Mass Index (BMI) post liquid nutritional supplementation
2. To know the change of Subjective Global Assessment (SGA) rank post liquid nutritional supplementation
3. To know the change of hemoglobin level post liquid nutritional supplementation
4. To know the change of prealbumin level post liquid nutritional supplementation

5. To know the change of Blood Urea Nitrogen (BUN) level post liquid nutritional supplementation
6. To know the change of lipid profile level post liquid nutritional supplementation
7. To know the change of blood glucose level post liquid nutritional supplementation
8. To know the change of body fat percentage post liquid nutritional supplementation
9. To know the change of handgrip strength test score post liquid nutritional supplementation

Methods

Study Design

This research is a single blind, randomized clinical trial method. Analysis will be conducted pre and post administration: control (standard liquid nutritional supplement as placebo), intervention (liquid nutritional supplement from hospital product) 2 times daily for 14 days.

Location and Time

This research will be conducted on Indonesia from August 2019 to December 2020

Population and Subject

Population

The population of this research is hospitalized patients with malnutrition in Indonesia

Subjects Criteria

- Inclusion criteria
  1. Subjects aged ≥ 18 years old to 60 years old
  2. Malnutrition hospitalized patient based on European Society for Clinical Nutrition and Metabolism (ESPEN) 2015 criteria
  3. Agreed to participate

- Exclusion criteria
  1. Malignancy
  2. Chronic kidney disease stage III-V
  3. Decompensated hepatic cirrhosis
  4. Allergic to milk or lactose intolerance
  5. Could not be randomised and participate in this study by clinical judgement

Drop Out Criteria

Drop out subjects are subjects who have signed the informed consent but decide to withdraw before research is completed

Estimated Sample Size

Minimum sample size is determined using the following equation for proportion equation.

$$N1 = N2 = \frac{(Z_\alpha\sqrt{2PQ} + Z_\beta\sqrt{P_1Q_1 + P_2Q_2})^2}{(P_1 - P_2)^2}$$

Description :

$Z\alpha = 1.96$ $Z\beta = 0.84$

P_1-$P_2 = 0.2$ $P_1 = 0.15$[10]

N1 = N2 = 62.41, thus with predicted drop out 10% the minimal sample for each group is 69 subjects

Randomization

Randomization is generated by computer and subjects will be given code and divided into two groups (control and intervention). Only researchers are blinded to treatment. Subjects can't be blinded since the taste between intervention and placebo is obvious.

Variables

Independent Variables

1. Intervention: administration of liquid nutritional supplement from hospital product 2 times daily
2. Control (placebo): administration of standard nutritional product 2 times daily

Dependent Variables

1. Body Mass Index (BMI)
2. Hemoglobin, prealbumin, Blood Urea Nitrogen (BUN), lipid profile, blood glucose from blood samples
3. Subjective Global Assessment (SGA) rank
4. Body fat percentage from Bioelectrical Impedance Analysis (BIA)
5. Handgrip strength score from handgrip strength test

Procedure

1. Eligibility assessment

   The subjects will be assessed for eligibility using inclusion and exclusion criteria.
2. Subjects sign the informed consent form
3. Randomization
4. Pre-administration
6. Before administration of liquid nutritional supplement either from commercial or hospital product or placebo based on randomization, subjects will be analysed for his/her BMI, hemoglobin, prealbumin, Blood Urea Nitrogen (BUN), lipid profile, blood glucose, Subjective Global Assessment (SGA) rank, body fat percentage and handgrip strength score. Subject will also be examined for his/her skinfold and mid upper arm circumference.
5. Administration (14 days)

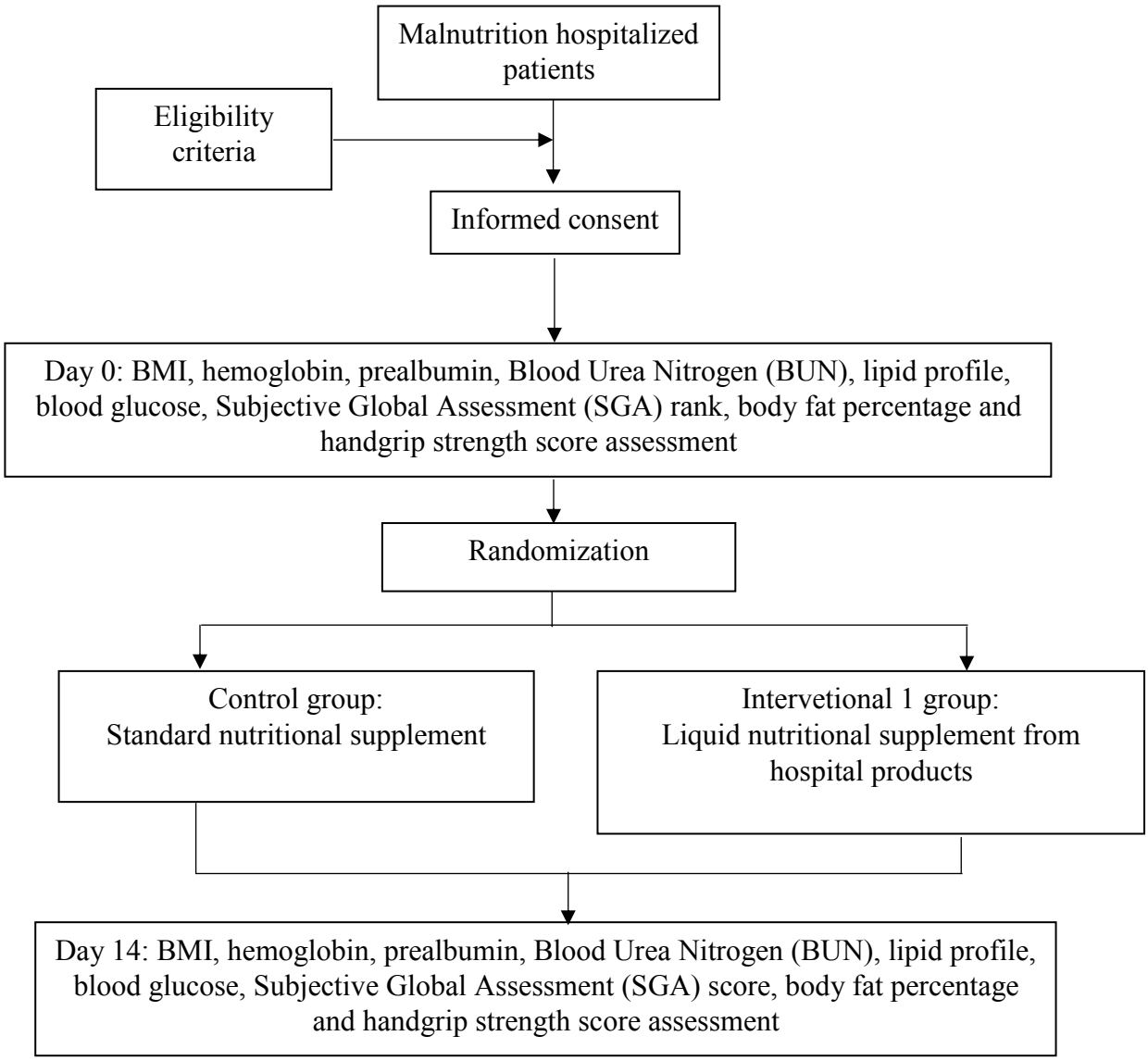
   Subjects will be given liquid nutritional supplement and placebo that will be taken two times daily for 14 days.
6. Compliance monitoring

   Compliance monitoring of administration is conducted by the investigators coordinating with his/her family, nurses and doctors in the hospital while patient is hospitalized
7. Post administration

   After 14 days, the subjects will be analysed for his/her BMI, hemoglobin, prealbumin, Blood Urea Nitrogen (BUN), lipid profile, blood glucose, Subjective Global Assessment (SGA) rank, body fat percentage and handgrip strength score.
8. Data analysis
   a. Normality analysis using Kolmogorov-Smirnov (Normally distributed if $p>0.05$)
   b. Bivariate analysis by comparing numeric data between two groups: if data is normality distributed using T-test, if not using Mann-Whitney test (significant if $p<0.05$)
   c. Bivariate analysis by comparing categorical data between two groups: if data is normality distributed using T-test, if not using Mann-Whitney test (significant if $p<0.05$)
   d. Bivariate analysis by comparing numeric data between preadministration and postadministration: if data is normality distributed using paired T-test, if not using Wilcoxon test (significant if $p<0.05$)

e. Bivariate analysis by comparing categorical data between preadministration and postadministration: if data is normality distributed using Mc Nemar test, if not using Wilcoxon test (significant if $p<0.05$)

Study flow chart



Ethical committee approval

Approval from the Ethical Committee at the Faculty of Medicine Universitas Indonesia must be obtained before starting the trial.

References

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