

The Tolerance of Organic Formula Milk and Its Fecal Microbiome Characteristic in Infants

Informed Consent

April 29th, 2021

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INFORMATION FOR STUDY SUBJECTS

Dearest parents.

Firstly, on the behalf of my research team, I, Bahrul Fikri, MD, Ph.D is the leader of the team. I will give an explanation of the research we will conduct, namely the Study of Tolerance of Organic Formula Milk and Its Impact on the Fecal Microbiota of Infants.

I will explain briefly about the bacteria in our intestine. A large number of bacteria exist in the human digestive tract. Bacteria make up the unique and complex gut environment by interacting with our bodies and influencing health and disease can arise in a variety of ways, including modification of the immune system. All of these functions may have control of inflammation not only in the gut but also in other parts of the body. An imbalance of gut bacteria or dysbiosis can start early in life. The increase in caesarean sections, formula feeding and use of antibiotics during pregnancy or infancy has a significant impact on the bacterial balance.

Next, I will explain the procedure of this study. First of all, I am looking for research subjects who meet the criteria and pick them randomly. After being given the explanation, and you agree to be involved in this research, then I will ask for a signature of consent to be involved in this research in a format called an informed consent. Then an interview will be conducted regarding the baby's food. Furthermore, you will be given notes to record eating patterns, signs of stomach pain, sleep quality, and the baby's condition. All babies will be fed with organic formula for 12 weeks. However, before giving the formula milk, measurements of nutritional status and samples of the baby's stool will be carried out. You will be asked to collect the stool while at home and then ask us (the research team) to collect the stool. Every month we will evaluate whether there is disease in the baby and signs of allergies and we will measure weight, body length, head circumference, and evaluate the journal that we provide to you.

Formula feeding can have side effects such as allergies to formula milk. Allergies can include atopic dermatitis, diarrhea, nausea, and vomiting. We will evaluate and treat if side effects are

found during this study for free. The examination is carried out under the guidance and supervision of the research team.

During the research, you are not charged. As this procedure is in accordance with clinical practice guidelines, all costs are researcher's expense. As a researcher, I will also bear the cost of BPJS health insurance for the baby during the study (maximum 5 months). Estimated time required from interview to completion of this examination is about 12 weeks.

Your participation in this research is voluntary without coercion, therefore, if you refuse to participate in this research, do not be afraid that you will lose your right to regular standard health services.

The data collected in this study will be stored in computer data. I will guarantee the confidentiality of your data. Only me as a researcher who knows your data. The results of this research will be published in limited scientific forums and national or international journals without showing your identity.

The results of this research will also be published both nationally and internationally.