

Informed Consent Form

The Role of Probiotics *L. Plantarum*, *S. thermophiles*, *B. bifidum* on Gut Inflammation, Bacterial Translocation, and CD4+ Cell Count in HIV Patients with Immunological Non-Responder (PIONIR)



INVESTIGATORS:

Principal : Erni Juwita Nelwan, MD, Ph.D

Others : Rina Agustina, MD, M.Sc., Ph.D

Prof. Marcellus Simadibrata, MD, Ph.D

FACULTY OF MEDICINE

Universitas Indonesia

Approved October 30th, 2017

INFORMED CONSENT FORM

Principal Investigator	: Erni J. Nelwan, MD, Ph.D		
Informant	:		
Subject Name	:		
Date of Birth (Age)	:		
Sex	:		
Address	:		
Phone Number (Cellphone)	:		
	TYPE OF INFORMATION	CONTENT OF INFORMATION	MARK
1	Title of The Study	The Role of Probiotics <i>Lactobacillus plantarum</i> , <i>Streptococcus thermophiles</i> , <i>Bifidobacterium bifidum</i> on Gut Inflammation, Bacterial Translocation, and CD4+ Cell Count in HIV Patients with Immunological Non-Responder: Double Blind Randomized Controlled Trial	
2	Objectives of The Study	To determine the effects of probiotics (good bacteria) <i>Lactobacillus plantarum</i> , <i>Streptococcus thermophilus</i> dan <i>Bifidobacterium bifidum</i> in HIV patients with immune response failure	
3	Methods of The Study	<p>You will be asked about HIV disease, physically examined, fill HIV symptoms index form, and have your blood tested for immune cells (CD4+ and Th17) level, viral load level, and bacteria translocation marker (16SrRNA) level. You will also have your stool tested for gut inflammation marker (fecal calprotectin) level and gut cells (colonocytes) level.</p> <p>We will take 12 cc of blood for test sample.</p> <p>You will get candies which you need to chew, 1 (one) tablet each day for 12 (twelve) weeks. ARV medication should be continued as usual, but should not be taken with the candies in the same time in a day. You will be examined physically and have</p>	



RSUPN Dr. Cipto Mangunkusumo

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Date of Birth :
(Please fill in the blank or put the ID sticker here)

		<p>the same laboratory tests as in the beginning of the study.</p> <p>This is a voluntary study. You may not participate in this study and it will not affect your treatment in Cipto Mangunkusumo National Central General Hospital.</p>	
4	Total of Subject	80 people	
5	Time of Study	1 (one) year with 12 weeks intervention	
6	Significances of Study (Including to Study Subjects)	<p>This study will bear the cost of laboratory study including CD4+, viral load, Th17, 16SrRNA levels by blood test and fecal calprotectin and colonocytes levels by fecal test. These tests will be conducted 2 (two) times.</p> <p>This study will help doctors in understanding HIV patients with immune response failure thus increasing the quality of practice.</p>	
7	Risks and Adverse Events of The Study	<p>The risk is pain at area of blood sampling.</p> <p>The adverse events that may occur including nausea, vomiting, diarrhea which may cause lack of body fluid, and lactobacilemia which may cause fever and severe stomachache.</p>	
8	Study Subject Inconvenience	You need to consume the candies with the flavor you do not like every day for 12 (twelve) weeks.	
9	Adverse Event Compensation	<p>If there is any lactobacilemia symptom, sepsis protocol will be executed and the probiotics treatment will be stopped.</p> <p>If there is lack of body fluid, a procedure of fluid therapy will be executed and probiotics treatment will be stopped.</p>	
10	Alternative Managements (if occurred)	You may not participate in this study and take the ARV treatment as usual.	

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	TYPE OF INFORMATION	CONTENT OF INFORMATION	MARK
11	Data Confidentiality	All your information will be kept and will not be given to any unauthorized person related to your treatment.	
12	Cost to Subjects	No cost will be borne by subjects	
13	Incentive for Subjects	No incentive will be given to subjects	
14	Name, Address, and Phone Number of Principal Investigator	Erni J. Nelwan, MD, Ph.D Divisi Penyakit Tropik dan Infeksi, Departemen Ilmu Penyakit Dalam, FKUI- RSCM Cellphone no: 021-3914190; 0811961229	

I have received information in page 1, 2, and 3 about the study conducted by Erni J. Nelwan, MD, Ph.D titled The Role of Probiotics *Lactobacillus plantarum*, *Streptococcus thermophiles*, *Bifidobacterium bifidum* on Gut Inflammation, Bacterial Translocation, and CD4+ Cell Count in HIV Patients with Immunological Non-Responder: Double Blind Randomized Controlled Trial. I clearly understand the information.

By signing this form, I agree to participate in the study voluntarily without any threat from anyone. I have right to cancel this agreement if I feel being harmed in any way.

Subject's Signature or Thumbprint

Date

Subject's Name

Subject's Guardian/Witness Signature

Date

Subject's Guardian/Witness Name

Note: Subject's Guardian/Witness Signature is needed if the subject is illiterate, having a decreased consciousness, having mental disorder, or under 18 years old.

Subject's Initial _____



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I have given the information to subject appropriately and truthfully about the study objectives, significances, procedure, and potential risk and uncomfortable situation which may happen (detailed information provided). I also have answered the questions related to the study in the best possible way.

Investigator's Signature

Date

Investigator's Name

Subject's Initial _____