PARTICIPANT INFORMATION FORM

Title	The ability of body lotion containing provitamin D_3 to reduce itching in patients with Chronic Kidney Disease undergoing routine hemodialysis
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This information sheet contains important information to help you decide whether or not to participate in this study. The investigator will explain about this study to you. Ask questions about anything unclear at any time. You can take this information sheet home to think about and discuss with family, relatives or friends.

A. Introduction to the body lotion under study

Itch is a very common and disturbing complaint for patients with Chronic Kidney Disease (CKD) undergoing hemodialysis (HD). CKD patients who undergo HD with itching have poor sleep quality which can affect the patient's quality of life.

Several studies have shown that dry skin, decreased vitamin D levels, and increased inflammatory markers (one of which is interleukin-31/IL-31) was found in CKD patients undergoing HD with itching. Several other studies have shown that itch intensity can be reduced by improving skin hydration through the use of a moisturizer (body lotion).

In November 2020, the Faculty of Medicine, Public Health and Nursing in collaboration with the Faculty of Pharmacy UGM and industrial partners launched the first body lotion product in Indonesia containing provitamin D_3. The use of body lotion containing provitamin D_3 is expected to reduce itch intensity, improve skin hydration, increase vitamin D levels, and reduce IL-31 levels in CKD patients undergoing routine HD.

B. Aim of the study

To determine the ability of body lotion containing provitamin D_3 to reduce itching in patients with CKD undergoing routine HD

C. Study Procedure

This study requires 82 (eightytwo) participants who will receive body lotion randomly. The duration of your participation in this study is approximately 5-6 weeks for 2 periods. After the screening period, you will enter the data collection period of 1 month. During the data collection period, you will receive 2 tubes of body lotion weighing 60 g each, with or without provitamin D_3, each 2 weeks apart as described below.

1. Screening period
   a. This period will last for 1-2 weeks with 3 meetings
   b. At the first meeting, the investigator will
      - explain about this study and ask whether you have complaints of itching
      - if you have complaints of itching, the investigator will give you the Participant Information and Consent Sheet
   c. At the second meeting, the investigator will
      - collect the Participant Information and Consent Sheet
      - if you agree to participate in this study, the investigator will look at your medical records and ask several questions to determine whether you meet the study participant criteria
   d. At the third meeting
      If you meet the study participant criteria
      - the investigator will give you the study participant identity card and the schedule for the next meeting
      - you are allowed to continue all of your usual medicines for CKD and your itching complaints
      - you will be asked to stop all medicines or other ingredients that are applied to the skin (for example herbal ingredients, special soaps, oils, powders, etc.) for your itching complaints, at least 2 weeks before your first scheduled appointment
2. Data collection period
   a. This period will last for 30 days with 5 meetings
   b. During this period, you will be randomly assigned to one of 2 (two) different groups to receive body lotion with or without provitamin D_3
   c. Anda diminta untuk selalu membawa dan menunjukkan kartu identitas subjek penelitian Anda pada setiap pertemuan di bawah ini (pertemuan pertama hingga terakhir)
   d. You are asked to always carry and show your study participant's identity card at each of the meetings below (first to last meeting)
   e. The first (day 0) and fourth (day 28) meetings will be held at the Hemodialysis Unit where you undergo routine hemodialysis. The nurse will check your study participant's identity card and take a 3 ml sample of your blood, right before you undergo hemodialysis
   f. The second (day 1), third (day 15), and fifth (day 29) meetings will be held at the Dermatology and Venereology Department Laboratory, Faculty of Medicine, Public Health and Nursing Universitas Gadjah Mada, Radioputro Building, 3rd floor, West Wing, according to the date and time that has been previously informed

g. At the second meeting the investigator will
   - check your study participant's identity card
   - ask your itch intensity
   - measure your skin hydration
   - give you the assigned body lotion (first tube) to use for 2 weeks
   - give you the participant's diary
   - determine the area to be applied with body lotion
   - explain to you how to apply body lotion and sunbathing, as well as filling in the participant's diary

h. At the third meeting the investigator will
   - check your study participant's identity card and participant's diary
   - ask your itch intensity
   - measure your skin hydration
   - collect the first tube of body lotion that has been given at the second meeting
   - give you the second tube of body lotion to use for 2 weeks

i. At the fifth (last) meeting the investigator will
   - check your study participant's identity card
   - mengumpulkan catatan harian dan sisa *body lotion* yang telah diberikan pada pertemuan ketiga collect your participant's diary and the second tube of body lotion
   - ask your itch intensity
   - measure your skin hydration

D. Participant's Obligation

As a study participant, you are obliged to follow the study instructions as written above. If something is not clear, you can ask further questions to the research team. During the study, you are not allowed to use topically applied drugs, herbal ingredients, special soaps, oils, body lotions and/or powders to reduce itching, without the knowledge and permission from the investigator.

E. Possible Side Effects

Body lotion containing provitamin D_3 has so far been widely used and does not provide significant side effects, but side effects still can occur in some people. The most frequently observed side effects are itching, stinging, and/ or pain; and may be accompanied by changes in skin color and/ or texture.

If you experience any side effects, you are asked to contact the investigator as soon as possible, write down these complaints in the subject's diary, and inform the research team at the next meeting.

F. Possible Benefits from participating in the Study

The immediate benefits are free body lotion, as well as free laboratory tests to determine skin hydration, vitamin D levels, and IL-31 levels.

G. Costs for participating in the Study

All study-related costs will be covered by the investigator.

H. Reimbursement for participating in the Study

You will received consumption and transportation allowance of IDR 25,000 (twenty-five thousand rupiah) for each meeting during the data collection period. You will not receive any reimbursement for meetings you did not attend.

I. Compensation of Side Effects

During the study, the investigator will provides free medical consultation for 2 weeks from the onset of side effects.

J. Personal Information and Confidentiality of Study Records

All information regarding your personal information/ identity will be kept confidential and will only be known by the research team. The research team will provide you with a subject identity card that will not reveal your name, ID number, address or other personal data. Study results will be published anonymously.

K. Voluntary Participation/ Withdrawal

You are free to choose to participate in this study without coercion. If you have decided to participate, you are also free to withdraw/ change your mind at any time without being subject to any fines or sanctions.

L. Early Termination of the Study

For your best interest or if you are unable to comply with the study procedures (for example, you are unable to attend the next meeting), the investigator may decide to terminate your participation in this study without your consent.

CONSENT FORM*

I certify that I have read the explanation form for this study. I certify that I have been given the opportunity to ask questions and all of my questions have been answered satisfactorily. I agree to participate in this study and comply with the terms as best I can.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving reasons, and that my decision does not affect my health care.

I agree to participate in this study.

I consent to the use of all anonymous data collected from me during this study, either individually or collected with other subjects, in the analysis of this study, in print publication, or for other purposes as determined by the investigator.

Date: _____

Study Participant Investigator

(_____) (_____)

*For participant

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Date: _____

Study Participant Investigator

(_____) (_____)

**For investigator