

# The ability of body lotion containing provitamin D3 to reduce itching in patients with chronic kidney disease undergoing routine hemodialysis

<b>Submission date</b> 27/12/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/01/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Itching (pruritus) is often experienced by patients with chronic kidney disease (CKD) undergoing hemodialysis (HD), resulting in poor sleep quality which can affect the patient's quality of life. Several studies have shown dry skin, decreased vitamin D levels, and increased inflammatory markers (one of which is interleukin-31/IL-31) in CKD patients undergoing HD with itching complaints. Several other studies have shown that the intensity of itching can be reduced by improving skin hydration through the application of body lotion. This study aims to determine the ability of body lotion enriched with provitamin D3 to reduce the intensity of itching in patients with CKD undergoing routine HD.

### Who can participate?

CKD patients aged 18-60 years old who have undergone routine hemodialysis two times a week for between 3 months and 10 years, and who have complaints of pruritus

### What does the study involve?

Participants would be instructed to apply the randomly assigned body lotion twice a day and to sunbathe twice a week for 4 weeks. A nurse would draw 3 ml of blood at the beginning and the end of the study. Itching intensity and skin hydration are measured at the beginning and after 2, and 4 weeks.

### What are the possible benefits and risks of participating?

The possible benefits would be free body lotions and free measurement of skin hydration, vitamin D levels, and IL-31 levels. The possible risks of using body lotion could be itchy, stinging, and/or pain at the site of application, while the risks of venous blood sampling could be phlebitis (inflammation of a vein) and/or thrombophlebitis (blood clot in a vein) at the sampling site

### Where is the study run from?

Gadjah Mada University (Indonesia)

When is the study starting and how long is it expected to run for?  
November 2021 to June 2023

Who is funding the study?

1. Duta Wacana Christian University (Indonesia)
2. Gadjah Mada University (Indonesia)

Who is the main contact?

Dr Arum Krismi, M.Sc, Sp.KK, penelitian.arumkrismi@gmail.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Ms Arum Krismi

### ORCID ID

<https://orcid.org/0000-0003-4276-3025>

### Contact details

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Jl. Imogiri Barat, Semail, Kel. Bangunharjo, Kec. Sewon, Daerah Istimewa Yogyakarta  
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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Correlation of changes in pruritus intensity with changes in serum IL-31 levels after application of body lotion enriched with provitamin D3 on patients with chronic kidney disease undergoing routine hemodialysis

### Study objectives

Body lotion enriched with provitamin D3 reduced the intensity of chronic kidney disease-associated pruritus on patients undergoing routine hemodialysis

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 23/12/2021, Medical and Research Ethics Committee (MHREC) Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada-Dr. Sardjito General Hospital (Gedung Radiopoetro Lt 2 Sayap Barat, Jl. Farmako, Sekip Utara, Yogyakarta, Indonesia, 55128; +62 (0)274 588688 ext. 17225, +62 (0)811 2666 869; mhrec\_fmugm@ugm.ac.id), ref: KE/FK/1375/EC/2021

### **Study design**

Multicenter interventional double-blinded randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Chronic kidney disease-associated pruritus in patients undergoing routine hemodialysis

### **Interventions**

Treatment: body lotion enriched with and without (placebo) provitamin D3

Randomization: simple randomization

Details of interventions:

1. 4 g (equal to 20,000 IU provitamin D3) per day, applied to one arm (1.5 g per application) and about 10 cm<sup>2</sup> area with the most intense itching (0.5 g per application), applied twice daily after bathing, for 28 days
2. Sunbathing twice weekly on the applicated arm

### **Intervention Type**

Supplement

### **Primary outcome(s)**

Pruritus intensity measured using a 24-hours Worst Itching Intensity Visual Analog Scale (WI-VAS) at baseline, 2, and 4 weeks

### **Key secondary outcome(s)**

1. Transepidermal water loss measured using a Tewameter at baseline, 2, and 4 weeks
2. Stratum corneum hydration measured using a corneometer at baseline, 2, and 4 weeks
3. Serum calcidiol levels measured using ELISA at baseline and 4 weeks
4. Serum IL-31 levels measured using ELISA at baseline and 4 weeks

### **Completion date**

30/06/2023

# Eligibility

## Key inclusion criteria

1. 18-60 years old
2. Complaints of pruritus with WI-VAS  $\geq 4$
3. Undergoing routine hemodialysis two times a week for  $\geq 3$  months and  $\leq 10$  years
4. Do not use any topical medical treatment for pruritus for at least 2 weeks before the study started. Medical treatment is medicine given by a doctor, both recorded in the Medical Record (MR) of the subject or recorded by the subject
5. Do not use any self-medication that is topically applied for pruritus for at least 2 weeks before the start of the study. Self-medication is non-medical treatment carried out by the subject alone or given by family, including but not limited to herbal concoctions, special soaps, oils, powders, and others
6. Agree to voluntarily participate in the study by signing the informed consent form

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

60 years

## Sex

All

## Total final enrolment

61

## Key exclusion criteria

1. Having one or more of the following diseases listed in subject MR and or obtained from anamnesis during subject screening:
  - 1.1. Hepatitis C virus infection
  - 1.2. Primary biliary cirrhosis
  - 1.3. Hodgkin lymphoma
  - 1.4. Cutaneous T-cell lymphoma
  - 1.5. Polycythemia vera
  - 1.6. HIV infection
  - 1.7. Atopic dermatitis
  - 1.8. Drug-induced hypersensitivity
  - 1.9. Insect bites reactions

- 1.10. Scabies
2. Having an impaired verbal and written communication
3. Having an impaired mobility

**Date of first enrolment**

10/05/2022

**Date of final enrolment**

06/05/2023

## **Locations**

**Countries of recruitment**

Indonesia

**Study participating centre**

**Panti Rapih Hospital**

Jl. Cik Di Tiro No.30, Samirono, Terban, Kec. Gondokusuman, Daerah Istimewa Yogyakarta  
Yogyakarta  
Indonesia  
55223

**Study participating centre**

**Dr. Sardjito General Hospital**

Jl. Kesehatan Jl. Kesehatan Sendowo No.1, Sendowo, Sinduadi, Kec. Mlati, Daerah Istimewa  
Yogyakarta  
Sleman  
Indonesia  
55281

**Study participating centre**

**Bethesda Hospital, Yogyakarta**

Jl. Jend. Sudirman No.70, Kotabaru, Kec. Gondokusuman, Daerah Istimewa Yogyakarta  
Yogyakarta  
Indonesia  
55224

**Study participating centre**

**PKU Muhammadiyah Hospital of Yogyakarta**

Jl. KH. Ahmad Dahlan No.20, Ngupasan, Kec. Gondomanan, Daerah Istimewa Yogyakarta  
Yogyakarta  
Indonesia  
55122

**Study participating centre****Rumah Sakit Akademik UGM Yogyakarta**

Jl. Kabupaten, Kranggan I, Trihanggo, Kec. Gamping, Daerah Istimewa Yogyakarta

Sleman

Indonesia

55291

**Study participating centre****PKU Muhammadiyah Hospital of Gamping**

Jl. Wates, Jl. Nasional III KM.5,5, Bodeh, Ambarketawang, Kec. Gamping, Daerah Istimewa

Yogyakarta

Sleman

Indonesia

55294

**Study participating centre****Rumah Sakit Umum Daerah (RSUD) Kota Yogyakarta**

Jl. Ki Ageng Pemanahan No.1-6, Sorosutan, Kec. Umbulharjo, Daerah Istimewa Yogyakarta

Yogyakarta

Indonesia

55162

## Sponsor information

**Organisation**

Gadjah Mada University

**ROR**

<https://ror.org/03ke6d638>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Universitas Kristen Duta Wacana

**Alternative Name(s)**

Duta Wacana Christian University, UKDW Yogyakarta, UKDW, DWCU

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Indonesia

**Funder Name**

Universitas Gadjah Mada

**Alternative Name(s)**

Gadjah Mada University, UGM

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Indonesia

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study are/will be available upon request from Arum Krismi (dr\_arumkrismi@staff.ukdw.ac.id). The type of data will be shared as requested in the format of excel, when all of the results are already published for about 5 years since the end of the study, to view only, with other researchers of the same field of study (CKD-associated pruritus), without consent from participants because the data would not contain participants' identity except their age and sex.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		05/01/2023	05/01/2023	No	Yes