

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

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See trial outputs table

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 cm² 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 measure

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

Secondary outcome measures

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

Overall study start date

08/11/2021

Completion date

30/06/2023

Eligibility**Key inclusion criteria**

1. 18-60 years old
2. Complaints of pruritus with WI-VAS ≥ 4
3. Undergoing routine hemodialysis two times a week for ≥ 3 months and ≤ 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

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

82

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
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55294

Study participating centre

Rumah Sakit Umum Daerah (RSUD) Kota Yogyakarta

Jl. Ki Ageng Pemanahan No.1-6, Sorosutan, Kec. Umbulharjo, Daerah Istimewa Yogyakarta
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55162

Sponsor information

Organisation

Gadjah Mada University

Sponsor details

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Sponsor type

University/education

Website

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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

Publication and dissemination plan

Planned publication in 'Advances in Chronic Kidney Disease'

Intention to publish date

30/06/2024

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?
Participant information sheet		05/01/2023	05/01/2023	No	Yes