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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

Registration date
06/01/2023

Overall study status
Completed

Last Edited
16/01/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
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^2 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 ≥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

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