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Sericin cream reduces pruritis in hemodialysis patients

Submission date
08/02/2012

Recruitment status
No longer recruiting

Registration date
16/02/2012

Overall study status
Completed

Last Edited
08/08/2014

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Uremic pruritus (UP) is a type of itching that occurs in chronic kidney disease (CKD) patients and substantially impairs their quality of life. It is caused by chronic inflammation and disturbance of the immune system. Since sericin has excellent moisturizing properties and can reduce inflammation, the aim of this study was to investigate the short-term safety and effectiveness of sericin cream for the treatment of UP in CKD patients.

Who can participate?
Hemodialysis patients over 18 years of age with CKD and mild to severe pruritis.

What does the study involve?
If you take part, first of all, you will be asked to not use any anti-histamine or antiprutitic medications, both oral and topical, during the study period. On the enrollment day, skin hydration, skin irritation and pigmentation from both legs and arms of subjects will be evaluated. Subjects will receive two creams, sericin cream (treatment) and cream base (control), on the day of enrollment. They will be requested to apply one cream on one side of their body (both on legs and arms) while the other cream will be applied on the opposite site of their body. All subjects will be shown how to topically apply the assigned treatment evenly over the area indicated twice daily for a period of 6 weeks. Questionnaires for evaluating itching and quality of life will be completed on the day of enrollment. Skin hydration, irritation and pigmentation will be evaluated again every 2 weeks. The questionnaires will be completed again after 6 weeks of treatment.

What are the possible benefits and risks of participating?
During the study your skin will be closely monitored for itching, dryness and irritation. Your skin should be more hydrated. There may be skin discomfort if you were in very warm and high humidity weather due to a little greasy skin. If you experienced any difficulty because of this, apply a smaller amount of cream will help relief the discomfort. Some patients may be allergic to silk protein, but this is very rare and the symptoms should not be severe and can be easily treated with a topical steroid. However, any skin reaction occurs will be closely monitored every 2 weeks during your visit.

Where is the study run from?
It is being organized by the Department of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Chulalongkorn University. There are two hospitals participating: Phramongkutklao Hospital and
Priest Hospital.

When is the study starting and how long is it expected to run for?
This study took place during March and September 2011.

Who is funding the study?
This research was supported by The National Research Council of Thailand and The Thailand Research Fund.

Who is the main contact?
Associate Professor Pornanong Aramwit (trial manager)
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of sericin cream on uremic pruritis in hemodialysis patients

Study objectives
1. Sericin cream can significantly increase skin hydration in hemodialysis patients compared to cream base
2. Sericin cream can significantly reduce skin irritation in hemodialysis patients compared to cream base
3. Sericin cream can decrease skin pigmentation in hemodialysis patients
4. Hemodialysis patients who receive sericin cream for the treatment of itching have better quality of life compared to hemodialysis patients who receive cream base for the treatment of itching

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Institute Review Board, Phramongkutklao Hospital, Thailand, 04/12 /2010, ref: 101H/53

Study design
Randomized double-blind placebo-controlled multicentre experimental study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Uremic pruritus in hemodialysis patients

Interventions
Patients received information regarding the study protocol, its rationale and the potential risks (in Thai language) as well as sericin cream and cream base formulation. Signed informed consent was obtained from all subjects after a thorough discussion of the protocol.

Split-body biometrologic assessments were performed. The patients were randomized into two groups using a computer-generated random sampling table in which the identity of those in each group was concealed from both the investigators and patients. The patients in the first group received sericin, degumming silk protein, cream (treatment) on their left arm and leg while the other side of the body received the cream base (control). The other group received

both sericin cream and the cream base, but on the opposite side of the body to the first group. All patients were shown how to topically apply the assigned treatment evenly over the area indicated twice daily after taking a shower for a period of 6 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sericin

Primary outcome measure
The level of skin hydration on both arms and legs was assessed using a Corneometer while skin irritation or erythema (measured by the redness of the skin) and skin pigmentation (measuring the melanin content) were assessed using a mexameter linked to Skin Diagnostic SD27 (Courage + Khazaka electronic GmbH, Köln, Germany). The same measuring probe is also used to quantify skin redness (erythema) and to determine skin pigmentation or the degree of skin tanning (melanin). Also, the irritating effects of cosmetics as well as the soothing effects of active agents can also be recorded. Each parameter was measured at least three times in the same randomized area and the mean value was used for analysis. During the study, all patients were advised to consume similar kinds and amounts of food and beverages. Different activities or travelling was to be avoided in order to reduce any confounding factors. The percentage changes in each parameter were calculated by subtracting the baseline score from the post-treatment score on weeks 2, 4 and 6 according to the following equation:
Percentage changes in each parameter = [(Pt - P0)/P0] * 100, where P0 is the value of each parameter at baseline (at the time of enrollment) and Pt is the value of each parameter during the follow-up period (2, 4 or 6 weeks). All measurements were performed in triplicate.

The severity of itching was systemically assessed in all patients on both the arms and legs, using the visual analogue scale (VAS), on the day of enrollment and every 2 weeks after treatment began. We used the VAS consisting of a 10-cm horizontal line with no scale markings. The patients were asked to mark the intensity of their itching on the scale, with the strongest possible level of itching marked on the right end of the line (10 cm) and no itching marked on the left end (0 cm).

Safety Monitoring
Any allergic reaction to the silk sericin cream, which can occur, was regularly evaluated by two dermatologists during each visit. The Naranjo algorithm was also used to determine the likelihood of whether an adverse drug reaction was actually due to the sericin cream or whether it was the result of other factors.

Secondary outcome measures
Patients Quality of Life
Quality of life was assessed using the Thai version of the Kidney Disease Quality of Life Short Form (KDQOL-SF) Version 1.3, which was used to evaluate the patients on the day of enrollment and after 6 weeks of treatment. Mean scores were compared for individual domain scores and for the three composite summary scores, namely the mental component score (MCS), the

physical component score (PCS) and the kidney-disease component score (KDCS). For the Hayes algorithm, the raw data obtained from the patients were first transformed into a pre-coded numerical value of 0-100, where a higher transformed score reflected a better quality of life.

Overall study start date
01/03/2011

Completion date
30/12/2011

Eligibility

Key inclusion criteria
1. All patients over 18 years of age with chronic kidney disease (CKD)
2. Patients who had received hemodialysis for at least three months were screened for this study
3. Mild to severe pruritis, according to the VAS, during the previous 6 weeks
4. Patients had to be willing to refrain from any antipruritic treatment, oral or topical, for a period of not less than 2 weeks prior to the start of the study.
5. Patients of both genders, regardless of comorbidities or prescribed medications

Any medication that had antipruritic effect was discontinued 1 week before the study. No change in the medication prescription of patients was required during this study, with the exception of concomitant antipruritic treatment.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 patients

Key exclusion criteria
1. Causes of pruritis from any other skin disease or from any medication
2. Patients with a history of silk protein allergy or who were allergic to any compounds in the formula
3. Patients who had biliary atresia, liver problems, cancer, metabolic disorders or other diseases related to systemic pruritis
4. Participants also left the project when they could not comply with the treatment, were unwilling to continue with the study or when the physician opined that other treatments were needed to relieve the symptoms.

Date of first enrolment

01/03/2011

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
Thailand

Study participating centre
Department of Pharmacy Practice
Bangkok
Thailand
10330

Sponsor information

Organisation
National Research Council (Thailand)

Sponsor details
196 Paholyotin Road
Chatuchak
Bangkok
Thailand
10900

Sponsor type
Research council

Website
http://www.nrct.go.th/index.php

ROR
https://ror.org/018wfhg78

Funder(s)

Funder type
Research organisation

Funder Name
National Research Council (Thailand), ref: 2553-27

Alternative Name(s)
National Research Council, Consiglio Nazionale delle Ricerche (IT), National Research Council of Italy, National Research Council (Italy), Italy, Consiglio Nazionale delle Ricerche, CNR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Funder Name
Thailand Research Fund (Thailand), ref: DBG5380039

Alternative Name(s)
TRF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Thailand

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	24/09/2012	Yes	No