ISRCTN13971661 https://doi.org/10.1186/ISRCTN13971661

Balneum Plus cream for the treatment of itchy skin in renal patients

Submission date
17/12/2014

Recruitment status
No longer recruiting

Registration date
15/01/2015

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Patients with kidney disease often suffer from itchy skin. Constant scratching can lead to skin damage and changes to the skin's appearance. Some patients are so troubled by itching that they can lose sleep, or even become depressed. We are not sure what causes the itching in kidney disease – it probably has many different causes, for example a build-up of toxins or blood salts in the skin. Many treatments are tried but they can often be unsuccessful, and currently there is no known cure for this distressing condition. The aim of this study is to see whether Balneum Plus works on the itch caused by kidney disease. Balneum Plus is already on the market and available to buy over-the-counter. It is used in other skin conditions like eczema and psoriasis, and it is safe to use in these conditions.

Who can participate?
Adult patients receiving haemodialysis for the treatment of End-Stage Renal Disease (ESRD) for at least 3 months

What does the study involve?
Patients are divided into two groups in a random fashion – meaning that each group will be similar in terms of age, type of kidney disease etc. One group will receive Balneum Plus and the other group will receive an inactive cream, called a placebo. Neither the patient nor the trial staff will know which cream is given to which patient. This method is used to make sure the study is scientifically fair.
The patient will be asked to apply the cream to areas of itchy skin, twice daily, for four weeks. Each week, we will ask each patient to score the intensity of their itching. At the beginning and end of the trial, each patient will fill in a questionnaire to assess the impact of the cream on their quality of life. Measurements and questionnaires will be filled in whilst each patient attends for their routine haemodialysis session so that no additional visits to the hospital are required. No additional blood tests, other than the patient's routine monthly blood tests will be required.

What are the possible benefits and risks of participating?
Once the study is finished, we will inform all participants of the results. If Balneum Plus is shown

to be useful in treating the itchy skin caused by kidney disease, we hope to be able to make an impact in treating this condition. There are not thought to be any risks in using the cream, but rigorous safety procedures will be in place

Where is the study run from?
Queen Alexandra Hospital, Portsmouth (UK)

When is the study starting and how long is it expected to run for?
January 2015 to April 2015

Who is funding the study?
Almirall Ltd (UK)

Who is the main contact?
Dr Jaqueline Nevols

Contact information

Type(s)
Public

Contact name
Dr Jacqueline Nevols

Contact details
Wessex Kidney Centre, Queen Alexandra Hospital
Portsmouth
United Kingdom
PO15 7HW

Additional identifiers

EudraCT/CTIS number
2014-005594-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHT/2014/107

Study information

Scientific Title
A Randomised, Double-Blind, Placebo-CONTrolled, Parallel Group Trial to Evaluate the Effectiveness and Safety of Balneum Plus in the Treatment of UraemIC PruriTus in Haemodialysis Patients

Acronym

The DONT ITCH Trial

Study objectives
Balneum Plus cream is superior to emollient control in the treatment of uraemic pruritus in haemodialysis patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Hampshire B Research Ethics Committee, 13/11/2015 ref: 15/SC/0478

Study design
Single centre randomised double-blind placebo-controlled parallel group trial

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
Uraemic pruritus in adult haemodialysis patients.

Interventions
Topical application of Balneum Plus cream or emollient control (as placebo) to affected areas, twice daily, for four weeks.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Balneum Plus cream. 3.0% urea and 5.0% Lauromacrogols as the active ingredients.

Primary outcome measure
Reduction in itch intensity as measured by visual analogue scale, at weekly intervals for 4 weeks.

Secondary outcome measures
Quality of life as measured by a validated questionnaire for itch in renal disease. The questionnaire will be filled in at baseline and then again after 4 weeks. Safety data in terms of adverse events will be collected weekly and usage requirements data collected at the end of the trial.

Overall study start date
01/01/2015

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Male or Female, aged 18 or above
2. Receiving haemodialysis for the treatment of End-Stage Renal Disease (ESRD) for at least 3 months
3. Participant is willing and able to give informed consent for participation in the study
4. Self reported symptoms of uraemic pruritus. Itch will be defined as at least 3 episodes of itch during the last 2 weeks, several times a day for more than 5 minutes and being bothersome
5. VAS score of at least 2cm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
58 patients.

Total final enrolment
58

Key exclusion criteria
1. Any other skin condition e.g. psoriasis, atopic dermatitis
2. Taking any oral medication for UP other than antihistamines e.g. opiates, gabapentin
3. Acute erythroderma, acute inflammatory, oozing or infected skin lesions
4. Use of topical skin medication containing any active ingredients (anything other than simple emollient)
5. Liver disease
6. Malignancy
7. Cognitive impairment that may impact on their ability to fill in the quality of life questionnaire

e.g. a previous diagnosis of dementia
8. Lack of a good understanding of English
9. Unwilling to apply the topical treatment as prescribed, including a previous history of poor-compliance with any treatment
10. Significant ongoing illness requiring inpatient treatment
11. Allergy to Balneum Plus or any of its ingredients
12. Pregnancy or Breastfeeding

Date of first enrolment
01/02/2015

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

Sponsor details
Queen Alexandra Hospital, Southwick Hill Road,
Portsmouth
England
United Kingdom
PO6 3LY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Industry

Funder Name
Almirall Ltd.

Results and Publications

Publication and dissemination plan
Planned to present the results at a national renal meeting and publish in a renal journal in due course.

Intention to publish date
30/11/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			17/06/2020	No	No
HRA research summary			28/06/2023	No	No
Results article		29/03/2023	13/02/2024	Yes	No