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

Submission date	Recruitment status	[X] Prospectively registered
17/12/2014	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
15/01/2015	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
13/02/2024	Skin and Connective Tissue Diseases	

### 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

Clinical Trials Information System (CTIS) 2014-005594-36

Protocol serial number 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

### Study type(s)

Treatment

### 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(s)

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

# Key secondary outcome(s))

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.

## 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

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### 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 poorcompliance 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

**United Kingdom** 

England

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

# Sponsor information

### Organisation

Portsmouth Hospitals NHS Trust

### **ROR**

https://ror.org/009fk3b63

# Funder(s)

### Funder type

Industry

### **Funder Name**

Almirall Ltd.

# **Results and Publications**

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

**Basic results** 

Output type Details
Results article

Date created Date added Peer reviewed? Patient-facing?

29/03/2023 13/02/2024 Yes 17/06/2020 No No No HRA research summary 28/06/2023 No No

Participant information sheet Participant information sheet 11/11/2025 No Yes