ISRCTN19139882 https://doi.org/10.1186/ISRCTN19139882

Long-term efficacy and safety of V0034 CR 01B cream in patients with moderate-to-severe uraemic xerosis

Submission date	Recruitment status	[ ] Prospectively registered
01/03/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/05/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/09/2008	Skin and Connective Tissue Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Patrick Dupuy

Contact details
Orfagen
Parc Technologique du canal
4 rue Marie Curie
BP 22132
Ramonville St Agne
France
31521

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V00034 CR 308 (ORF)

Study information

Scientific Title

Study objectives
Primary objective:
To demonstrate the long-term efficacy (response to treatment during initial therapy, time to relapse without treatment, durability and lesional recurrence during maintenance therapy) of V0034 CR 01B cream on uraemic xerosis in the real-life setting.

Secondary objectives:
1. To assess the local tolerance of V0034 CR 01B after long-term use
2. To assess the patient benefit and acceptability of V0034 CR 01B

Please note that as of the 18th January 2008 this record was updated. Changes are written under the relevant sections under the date 18/01/2008. Please also note that the anticipated end date of this trial has been extended to 30/09/2008. The previous anticipated end date of this trial was 30/09/2007. Please also note that the following countries of recruitment have been added to this record as of 18/01/2008: Hungary, Czech Republic, Latvia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval from:
1. Comités de Protection des Personnes, Sud Méditerranée IV, Hôpital St Eloi (France), approved on 25th August 2006
2. Sächsische Landesärztekammer Ethics Committee (Germany), approved on 14th November 2006
3. Commission of bioethics at Wroclaw Medical University (Poland), approved on 30th September 2006
4. Center of Katerini, General Hospital of Katerini (Greece), approved on 20th October 2006
5. Center of Szeged, University of Szeged (Hungary), approval pending
6. Center of Praha, Charles University School of Medicine (Czech Republic), approval pending
7. Center of Riga, Latvian Dermatology Institute Ltd Clinic (Latvia), approval pending

Study design
Periods I + II: randomised, double blind, parallel group study; period III: open-labelled, non-controlled, one-arm study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Uraemic xerosis

Interventions
The study will comprise three periods:
Period I: randomised, vehicle-controlled, double-blind, two-parallel group, comparative study (initial treatment period) - once daily application of V0034 CR 01B or its vehicle
Period II: randomised, double blind, two-parallel group study (treatment-free follow-up) - no topical treatment
Period III : open-labelled, non-controlled, one arm study (maintenance treatment period) - V0034 CR 01B application at dosage ad libitum

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
V0034 CR 01B cream

Primary outcome measure
1. Treatment response of xerosis on five test areas (right lower leg, left lower leg, forearm having no arterio-venous shunt, chest, dorsum of the neck), using a defined physicians five-point severity scale (Gammal severity scale). Treatment response will be defined as a score of zero or one on all test areas at the end of Period I, and a reduction of at least two grades on at least one test area (primary efficacy parameter, Period I).
2. Time to relapse, as defined as the time up to which patients have at least one test area with a severity score of at least two during the treatment-free follow-up (Period II). Only patients with no persisting lesions on day 28 will be evaluated for this parameter.

Secondary outcome measures
1. Change from baseline of the Gammal severity score of the five test areas, as assessed by the physicians. Total severity score (sum of scores of the test areas) and separate scores by test area will be presented. Recurrence rate (i.e. proportion of patients with at least one test area with a score of at least two) will be accounted during Period III.
2. Scaling measurement (mean optical density of squames [MOD], total surface area of squames [SURFT]) on one lower leg made by the physician, using D-Squame
3. Assessment of the global severity of xerosis and pruritus made by the patients, using 10-cm Visual Analogue Scales (VAS)
4. Life quality assessment performed by 12-item Short Form health survey (SF-12) (generic scale) and Dermatology Life Quality Index (DLQI) scales, made by the patients
5. Global agreement of the test product by the patients on efficacy and ease of use, using a four-point scale (very satisfactory to not satisfactory at all)

Overall study start date

18/12/2006

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Patients of both sexes, of at least 18 years of age
2. Women of childbearing potential having a reliable contraceptive method
3. Patients undergoing maintenance renal dialysis (MRD), i.e. either haemodialysis or peritoneal dialysis, due to chronic renal failure
4. Patients whose xerosis is related to their renal insufficiency status (uraemic xerosis)
5. Patients suffering from xerosis with a severity score of at least two, on at least one of the five tests areas (right lower leg, left lower leg, forearm with no arterio-venous shunt, chest, dorsum of the neck)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240 patients

Key exclusion criteria
1. Patients under 18 years of age
2. Women with childbearing potential having a positive pregnancy test at baseline
3. Patients undergoing renal dialysis for another reason than chronic renal insufficiency
4. Patients whose xerosis is due to another reason than their MRD status
5. Patients suffering from mild xerosis (i.e. score less than two on all the xerotic test areas)
6. Patients with a known history of allergy to one of the ingredients contained in the test product
7. Patients with an intercurrent condition which may interfere with a good conduct or the study parameters of the study
8. Patients treated with any other emollient/moisturising topical preparation within the seven days prior to study entry
9. Patients who participated in a study within the three months prior to study entry
10. Patients who are not affiliated to health insurance
11. Patients who are not able or willing to follow the study instructions

Date of first enrolment
18/12/2006

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Czech Republic

France

Germany

Greece

Hungary

Latvia

Poland

Study participating centre
Orfagen
Ramonville St Agne
France
31521

Sponsor information

Organisation
Orfagen (France)

Sponsor details
Parc Technologique du canal
4 rue Marie Curie
BP 22132
Ramonville St Agne
France
31521

Sponsor type
Industry

Website
http://www.orfagen.com/homepage/0,7134,20877876_0_0_fr_FR_0,00.html?vid=20878546

Funder(s)

Funder type
Industry

Funder Name
Orfagen (France)

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