ISRCTN71227633 https://doi.org/10.1186/ISRCTN71227633

An Open-Label Adrenal Suppression Study of Fluocinonide 0.1% Cream in Pediatric Subjects with Atopic Dermatitis

Submission date
29/03/2006

Registration date
20/04/2006

Last Edited
08/05/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lester Fahrner

Contact details
Christie Clinic on University
101 West University Avenue
Champaign
Illinois
United States of America
61820

Additional identifiers

Protocol serial number
MP-0201-07

Study information

Scientific Title

Study objectives
The primary objective of the study was to evaluate the potential of fluocinonide 0.1% cream to suppress the hypothalamic-pituitary-adrenal (HPA) axis, when applied once daily or twice daily for 14 days by pediatric subjects with atopic dermatitis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Essex Institutional Review Board, Inc. on 23/06/2004

Study design
Multicenter, multiple-dose, open-label study with four sequential age cohorts

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atopic dermatitis

Interventions
Fluocinonide 0.1% applied, for 14 days, once daily versus twice daily.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Evaluate the effect of fluocinonide 0.1% cream to suppress the HPA axis

Key secondary outcome(s))
1. Serum cortisol levels before and after stimulation with cosyntropin
2. Skin safety evaluations (signs and symptoms of skin atrophy, telangiectasia, and pigmentation changes)
3. Vital signs and weight
4. Evaluation of any adverse events reported during the study

Completion date
15/03/2005

Eligibility

Key inclusion criteria
1. Ages 3 months to less than 18 years
2. Clinically diagnosed atopic dermatitis greater than or equal to 20% of total body surface area (BSA)
3. Not pregnant
4. Using acceptable birth control

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Pregnant or nursing
2. Use of concomitant therapies for atopic dermatitis
3. Untreated bacterial, tubercular, fungal or viral lesion of the skin
4. Known sensitivity to any constituents of the study drug
5. Significant disease of the hepatic, renal, endocrine, musculoskeletal or nervous system or any gross physical impairment
6.Irregular sleep schedules
7. History of chronic drug or alcohol abuse
8. Investigational treatment within 30 days prior to study
9. Being treated for or history of melanoma in the past five years

Date of first enrolment
21/06/2004

Date of final enrolment
15/03/2005

Locations

Countries of recruitment
United States of America

Study participating centre

Christie Clinic on University
Illinois
United States of America
61820

Sponsor information

Organisation
Medicis Pharmaceutical Corporation (USA)

ROR
https://ror.org/01zgpn844

Funder(s)

Funder type
Industry

Funder Name
Medicis Pharmaceutical Corporation

Results and Publications

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:	01/12/2006		Yes	No