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

Submission date	Recruitment status	[_] Prospectively registered
29/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/04/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/05/2008	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Evaluate the effect of fluocinonide 0.1% cream to suppress the HPA axis

Secondary outcome measures
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

Overall study start date
21/06/2004

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

Age group
Child

Lower age limit
3 Months

Upper age limit
17 Years

Sex
Both

Target number of participants
120 - 30 per cohort

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)

Sponsor details
8125 North Hayden Road
Scottsdale
Arizona
United States of America
85258

Sponsor type
Industry

ROR
https://ror.org/01zgpn844

Funder(s)

Funder type
Industry

Funder Name
Medicis Pharmaceutical Corporation

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:	01/12/2006		Yes	No