

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

**Submission date**

29/03/2006

**Recruitment status**

No longer recruiting

**Registration date**

20/04/2006

**Overall study status**

Completed

**Last Edited**

08/05/2008

**Condition category**

Skin and Connective Tissue Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ 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

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?
<a href="#">Results article</a>	Results:	01/12/2006		Yes	No