A prospective pediatric longitudinal evaluation to assess the long-term safety of tacrolimus ointment for the treatment of atopic dermatitis.

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Ethical review	-
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON30879

Source
ToetsingOnline

Brief title
APPLES

Condition

- Epidermal and dermal conditions

Synonym
Atopic Dermatitis

Research involving
Human

Sponsors and support

Primary sponsor: Astellas Pharma

Source(s) of monetary or material Support: Farmaceutisch bedrijf

Intervention

Keyword: Atopic dermatitis, Longitudinal, Pediatric, Safety

Outcome measures

Primary outcome

Primary study parameters are the frequency of all Serious Adverse Events

(SAEs), including but not limited to the following:

- the total systemic malignancies diagnosed more than 6 months after the

initiation of tacrolimus ointment treatment

- Hodgkin's / Non-Hodgkin's lymphoma diagnosed more than 6 months after the

initiation of tacrolimus ointment treatment, and

- Cutaneous malignancies (melanoma and non-melanoma skin cancer) diagnosed more

than 6 months after the initiation of tacrolimus ointment treatment

Secondary outcome

Not applicable.

Study description

Background summary

December 2000, the Food and Drug Administration (FDA) approved Protopic® (tacrolimus ointment), 0.03% Protopic® in children and 0.1% Protopic® in adults, for the treatment of atopic dermatitis (AD). October 2001 the EMEA (European Agency for the Evaluation of Medicinal Products) also approved both formulations for the same indication.
As part of the approval process, both the FDA and the EMEA requested a post-marketing commitment regarding the safety of long-term use of tacrolimus ointment in pediatric AD subjects.

After long negotations with the FDA in March 2005 the final protocol was

released. Initially only the USA, Germany, United Kingdom and Ireland were involved. Recently it has been decided to expand the number of participating countries. Among those countries are the Netherlands, Poland and Canada.

Study objective

The objective of the study is to assess the long-term safety of tacrolimus ointment 0.03% or 0.1% in the treatment of subjects with atopic dermatitis under actual use conditions, including the risk of developing cutaneous or systemic malignancies. In this study a large cohort of subjects who have used tacrolimus for the first time before the age of 16 years will be followed on the long-term.

Study design

In this study approximately 8,000 subjects will be enrolled, who have used tacrolimus for the first time before the age of 16 years. Each subject will be followed for 10 years after enrollment.
During these follow-up period there will be a yearly physical examination and every two years in combination with a dermatological examination.
In addition each subject will be interviewed twice a year either by telephone or by mail (or internet) to answer a short list of questions. The choice is up to the subject. These questions concern the subject status, medication, physician office visits scheduled and biopsies and hospitalizations.

Study burden and risks

In principle there is no burden and risks involved in this study. There will be no study medication provided to the subjects. For study purposes there will be no bloodsampling or other invasive procedures.
The only burden for subjects are the yearly visits to the physician and twice a year answering a short questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1) Subject has/ had atopic dermatitis
2) Subject has applied tacrolimus ointment 0.03% or 0.1% for at least 6 weeks either continuously or intermittently. This may include subjects who have been enrolled in previous tacrolimus ointments studies and or subjects with commercial product exposure prior to study enrollment.
3) Subject age at first tacrolimus ointment exposure is /was < 16 years.
4) Subject / caregiver has given written informed and assent.
5) Subject / caregiver agrees to comply with the program requirements including an annual physical examination and biennal dermatological exam and agrees to be contacted and provide information.

Exclusion criteria

Not applicable

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2008
Enrollment:	120
Type:	Actual

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00475605
CCMO	NL18631.018.07