A randomized, double-blind, placebo-controlled, parallel group study evaluating efficacy and safety of QAW039 in the treatment of patients with moderate to severe atopic dermatitis (CQAW039X2201)

Published: 16-07-2013
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Primary objective: To evaluate the efficacy of once daily doses of QAW039, as measured by EASI after 12 weeks of treatment, relative to placebo, in adult patients with moderate to severe AD. To evaluate safety and tolerability.Secondary objectives:...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON40359

Source
ToetsingOnline

Brief title
CQAW039X2201

Condition

- Allergic conditions
- Skin and subcutaneous tissue disorders NEC

Synonym
atopic dermatitis; eczema

Research involving
Human

Sponsors and support

Primary sponsor: Novartis Pharma BV
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Keyword: atopic, dermatitis, QAW039

Outcome measures

Primary outcome

EASI score week 12, adverse effects.

Secondary outcome

EASI score week 4 and 8.

Study description

Background summary

Atopic dermatitis (AD) is an itching, chronically relapsing skin condition. It is maily localized in the face, behind the ears, on the hairy part of the head, on the trunk and arms and legs. The onset is mostly at the age of 3 months. After the age of 10 years mainly the hands, feet, elbows and knees are affected. In some adults the disease is mainly localized in the face and neck. It is often associated with elevated serum IgE levels and a personal or family history of allergies, allergic rhinitis, and asthma. The prevalence of AD has been reported to be at least 10-15% of children in Europe.
Topical corticosteroids are the mainstay of therapy but their value in patients with extensive disease is limited by the need for topical application and short-term use. Long-term use of topical corticosteroids is not recommended due to the potential to cause local and systemic side effects (e.g. skin atrophy, impairment of hypothalamic-pituitary-adrenal axis function, and growth retardation). Treatment options for patients who are not controlled with topical treatments include phototherapy, methotrexate, and cyclosporine.
QAW039 is a highly selective and potent oral antagonist of prostaglandin D2 (PGD2) that binds to the CRTh2 receptor. CRTh2 inhibitors have been shown to exert clinical efficacy in asthma and allergic rhinitis. Circulating T-cells

and eosinophils of atopic dermatitis patients express CRTh2 receptors correlating to disease severity. Please see the Investigator*s Brochure for more information on the mechanism of action and characteristics of QAW039. This non-confirmatory clinical study will assess the efficacy and safety of QAW039 in adult patients with AD over 12 weeks of treatment.

Study objective

Primary objective: To evaluate the efficacy of once daily doses of QAW039, as measured by EASI after 12 weeks of treatment, relative to placebo, in adult patients with moderate to severe AD. To evaluate safety and tolerability.
Secondary objectives: To evaluate the efficacy of QAW039, as measured by EASI, after 4 and 8 weeks of treatment.

Study design

Randomized, double-blind placebo-controlled parallel group, phase II study.
Randomization (3:1) to:
* QAW039 450 mg orally, once daily.
* Placebo.
Screening 4 weeks, treatment 12 weeks, follow-up 8 weeks.
Rescue medication.
Approx. 92 patients.

Intervention

Treatment with QAW039 or placebo.

Study burden and risks

Risk: Adverse effects of study medication. Changes in current asthma medication. Stepping down budesonide.
Burden: 10 visits in approx. 24 weeks.
Blood tests 10 times (5-65 ml/occasion, 345 ml in total).
Pregnancy test 4 times.
Skin test 4 times.
Skin biopsy 2 times.
ECG 6 times.
Questionnaires (4) 7 times.
Daily diary (medication use and symptoms).
When no positive result of atopy patch test was found at baseline (Visit 3), atopy patch test will not be performed at Visit 7/8 and Visit 7 may be dropped.
Optional substudies:
* Pharmacogenetic blood test (10 ml).
* Biomarker tests: (3 times extra skin biopsy.

* Photographs of lesions in the face.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Male or female adults aged 18-65 years.
* Atopic dermatitis (AD) (see protocol page 34 for details).
* Stable AD, EASI score *15 at screening.
* Has been treated with topical corticosteroids or topical calcineurin inhibitors on at least one occasion or could not use topical drugs (due to contraindications, side effects, etc.) and are candidates for or have previously received systemic treatment.

Exclusion criteria

* History of serious allergic reactions to any allergen (see protocol page 35 for details).
* Clinically significant ECG abnormalities (see protocol page 35 for details).
* History of long QT syndrome or QTc measured at Visit 2 (Fridericia method) is prolonged (>450 ms for males and females).
* Use of topical prescription treatment within 2 weeks prior to initial dosing of study drug. Exception: see protocol page 35 for details.
* Recent previous systemic treatment. See protocol page 35 for types of treatment en wash-out.
* Patients on maintenance immunotherapy who either began their allergen specific immunotherapy regimen or had a clinically relevant change to their immunotherapy within 1 month prior to granting informed consent.
* High dose statin therapy (see protocol page 36 for details).
* Excessive exposure to UV light in the 3 weeks prior to screening (see protocol page 36 for details).
* BMI < 17 or > 40 kg/m2.
* Pregnancy and breast feeding. Inadequate contraception, if relevant.
* Serious co-morbidities (see protocol page 37 for details).

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2013
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	QAW039
Generic name:	QAW039

Ethics review

Approved WMO Date:	16-07-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	13-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2012-005321-78-NL
CCMO	NL45361.060.13