An Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Reslizumab (3.0 mg/kg) as Treatment for Patients With Eosinophilic Asthma Who Completed a Prior Cephalon Sponsored Study in Eosinophilic Asthma

Published: 10-05-2011
Last updated: 27-04-2024

The primary objective of the study is to evaluate the long-term safety of reslizumab at a dosage of 3.0 mg/kg every 4 weeks for approximately 24 months in pediatric and adult patients with eosinophilic asthma as assessed. The secondary objectives of...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON36581

Source
ToetsingOnline

Brief title
Cephalon C38072/3085

Condition

- Bronchial disorders (excl neoplasms)

Synonym
eosinophlic asthma

Research involving

Human

Sponsors and support

Primary sponsor: Cephalon
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Eosinophilic Asthma, Lung Function, Reslizumab

Outcome measures

Primary outcome

* adverse events will be evaluated throughout the study

* chemistry, hematology, and urinalysis tests (except for urine beta human

chorionic gonadotropin

[*-HCG] test conducted predose every 4 weeks) will be performed at baseline

(end-of-treatment visit

of previous double-blind study), at weeks 4, 8, and 24, and every 24 weeks

thereafter until

end-of-treatment visit/early termination, and 90 days after the

end-of-treatment visit for blood

eosinophils.

* vital sign measurements, brief physical examinations, and concomitant

medication usage will be

assessed every 4 weeks throughout the study, and 90 days after the

end-of-treatment visit.

* antibodies to reslizumab will be assessed every 24 weeks until

end-of-treatment visit/early

termination

Secondary outcome

* change from baseline in pulmonary function test results as measured by FEV1,

%FEV1, FVC, and

FEF25-75% every 4 weeks for 16 weeks, at 24 weeks, and every 12 weeks

thereafter until

end-of-treatment visit, or early termination

* change from baseline in beta-agonist use every 4 weeks for 16 weeks, at 24

weeks, and every 12

weeks thereafter until end-of-treatment visit, or early termination

* change from baseline in ASUI every 4 weeks for 16 weeks, at 24 weeks, and

every 12 weeks

thereafter until end-of-treatment visit, or early termination

* change from baseline in ACQ score every 4 weeks for 16 weeks, at 24 weeks,

and every 12 weeks

thereafter until end-of-treatment visit, or early termination

* change from baseline in AQLQ score every 24 weeks until end-of-treatment

visit, or early termination

Study description

Background summary

Some individuals have a type of asthma made worse by an unusual increase in white blood cells in their lungs which may cause chronic airway inflammation. These cells are called eosinophils and may be caused by high levels of a normal protein called interleukin 5 (IL 5). Researchers hope that reslizumab blocks

the action of the IL 5 protein and therefore lowers the level of these white blood cells in the lungs.
Reslizumab is an investigational drug, a drug that is being tested and is not approved for sale yet. Researchers hope that Reslizumab improves asthma control in subjects with active asthma and eosinophilic airway inflammation. In an earlier research the action of Reslizumab has been compared with placebo.
This is an open-label extension study. Patients will receive the same 4-weeks treatment as in the 3081 study, for 2 additional years after they start with the extension phase.

Study objective

The primary objective of the study is to evaluate the long-term safety of reslizumab at a dosage of 3.0 mg/kg every 4 weeks for approximately 24 months in pediatric and adult patients with eosinophilic asthma as assessed. The secondary objectives of the study are as follows:
* pulmonary function test results, as measured by forced expiratory volume in 1 second (FEV1), percent
predicted forced expiratory volume in 1 second [%FEV1], forced vital capacity (FVC), forced
expiratory flow at 25% to75% FVC (FEF25-75%) every 4 weeks for 16 weeks, at 24 weeks, and every
12 weeks thereafter throughout the study
* beta-agonist use every 4 weeks for 16 weeks, at 24 weeks, and every 12 weeks thereafter throughout
the study
* asthma symptom score (Asthma Symptom Utility Index [ASUI]) every 4 weeks for 16 weeks, at
24 weeks, and every 12 weeks thereafter throughout the study
* Asthma Control Questionnaire (ACQ) every 4 weeks for 16 weeks, at 24 weeks, and every 12 weeks
thereafter throughout the study
* Asthma Quality of Life Questionnaire (AQLQ) every 24 weeks throughout the study

Study design

Phase III, open-label extension study

Intervention

Reslizumab (3,0 mg/kg) every 28 days (±7 days), for approximately 24 months intravenously by infusion.

Study burden and risks

Reslizumab can have the following side-effects: headache; fatigue (feeling tired); nausea; upper respiratory tract infection (i.e., cold symptoms); myalgia (muscle tenderness or pain).

Summary of procedures:
- short physical exam (each visit, at screening/baseline and end of study visit an extended physical exam will be performed)
- length and weight (every 16 weeks)
- measurement of vital signs (each visit)
- lung function tests (visit 1 - 5, 7, and further every 12 weeks)
- blood tests for lab study (visit 1 - 3, 7, and further every 24 weeks)
- urine pregnancy test (every visit)
- questionnaires regarding asthma symptoms (visit 1 - 5, 7, and further every 12 weeks)
- urine analysis (visit 1 - 3, 7, 13, and further every 24 weeks)

Contacts

Public
Cephalon

41 Moores Drive, Aegon Building
PA 19355 Frazer
US
Scientific
Cephalon

41 Moores Drive, Aegon Building
PA 19355 Frazer
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(a) The patient is male or female, 12 through 75 years of age, with a previous diagnosis of asthma and who completed treatment in a Cephalon-sponsored, double-blind, placebo-controlled study in patients with eosinophilic asthma.
(b) Patient must have completed treatment in a previous Cephalon-sponsored double-blind asthma exacerbation study or received at least 2 doses of study drug treatment in a pulmonary function study.
(c) The patient must be willing and able to comply with study restrictions and to remain at the clinic for the required duration during the study period, and willing to return to the clinic for the follow-up evaluation as specified in this protocol.

Exclusion criteria

- The patient has a clinically meaningful comorbidity that would interfere with the study schedule or procedures, or compromise the patient*s safety.
- The patient has another confounding underlying lung disorder (eg, chronic obstructive pulmonary disease, pulmonary fibrosis, or lung cancer).
- The patient is a current smoker.
- The patient has a current infection or disease that may preclude assessment of asthma.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Will not start

Enrollment:	6
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	Reslizumab

Ethics review

Approved WMO Date:	10-05-2011
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	13-07-2011
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	20-10-2011
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	12-06-2014
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	13-01-2015
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
EudraCT	EUCTR2010-024540-15-NL
ClinicalTrials.gov	NCT01290887
CCMO	NL35342.096.11