A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to evaluate the Efficacy and Safety of Reslizumab (0.3 or 3.0 mg/kg) as Treatment for Patients (12-75 Years of Age) with Eosinophilic Asthma.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON36320

Source
ToetsingOnline

Brief title
Cephalon C38072/3081

Condition

- Bronchial disorders (excl neoplasms)

Synonym
eosinophlic asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Eosinophilic Asthma, Lung Function, Reslizumab

Outcome measures

Primary outcome

The primary efficacy variable for this study is the change from baseline to endpoint in FEV1.

Secondary outcome

The secondary efficacy variables and endpoints for this study are as follows:

* change in lung function as measured by %FEV1, FVC, and FEV25-75% from baseline to weeks 4, 8, 12, 16, and endpoint (endpoint is week 16 or early withdrawal)

* change in beta-agonist use from baseline to weeks 4, 8, 12, 16, and endpoint

* change in blood eosinophil count from baseline to weeks 4, 8, 12, 16, and endpoint

* change in asthma symptom score from baseline to weeks 4, 8, 12, 16, and endpoint

* change in ACQ score from baseline to weeks 4, 8, 12, 16, and endpoint

* change in AQLQ score from baseline to week 16 and endpoint

* change in sputum eosinophil levels from baseline to endpoint

* change in biomarkers from baseline to endpoint

* change in the presence or absence of nasal polyps

* adverse events throughout the study

* clinical laboratory tests assessed at weeks 4, 8, 12, 16, and 90 days after

the end-of-treatment evaluation

* vital signs (blood pressure, pulse, body temperature, and respiratory rate)

measurements at weeks 4, 8, 12, 16, and 90 days after the end-of-treatment

evaluation

* physical examinations at weeks 4, 8, 12, 16, and endpoint

* ECG recording at week 16 and endpoint

* concomitant medication usage throughout the study

* measurement of anti-drug antibodies at week 16 and endpoint

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. This will be studied in this research.

Study objective

The primary objective of this study is to determine whether reslizumab, at a dosage of 0.3 or 3.0 mg/kg administered once every 4 weeks for a total of 4 doses, is more effective than placebo in improving lung function in patients

with eosinophilic asthma as assessed by the change from baseline in forced expiratory volume in 1 second (FEV1). The secondary objectives of the study are as follows:
* to evaluate the efficacy of reslizumab treatment compared with placebo treatment in patients with eosinophilic asthma as assessed by the effect of reslizumab on the following:
* lung function as measured by percent predicted forced expiratory volume in 1 second (%FEV1), forced vital capacity (FVC), and forced expiratory flow at 25% to 75% of FVC (FEF25-75%)
* beta-agonist use
* blood eosinophil count
* asthma symptoms as measured by the Asthma Symptom Utility Index (ASUI)
* asthma control as measured by the Asthma Control Questionnaire (ACQ)
* quality of life as measured by the Asthma Quality of Life Questionnaire (AQLQ)
* to characterize the pharmacokinetics of reslizumab using serum concentrations obtained prior to and after each infusion
* to characterize the relationship between serum concentrations of reslizumab and measures of efficacy and safety
* to evaluate the safety and tolerability of reslizumab treatment as assessed by the following:
* occurrence of adverse events throughout the study
* clinical laboratory (serum chemistry, hematology, urinalysis) test results at specified times throughout the treatment period or early withdrawal
* vital signs (systolic and diastolic blood pressures, pulse, body temperature, and respiratory rate) measurements at weeks 4, 8, 12, and 16 or early withdrawal
* physical examination findings at weeks 4, 8, 12, and 16 or early withdrawal
* 12-lead electrocardiography (ECG) findings at week 16 or early withdrawal
* concomitant medication usage throughout the study
* measurement of anti-drug antibodies at weeks 8 and 16 or early withdrawal
* as an exploratory objective, to characterize potential biomarkers in sputum and/or blood that may more effectively identify patients who have this phenotype of asthma.

Study design

Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study.

Intervention

Reslizumab administered intravenously at 0.3 mg/kg or 3 mg/kg once every 4 weeks, or placebo.

Study burden and risks

Reslizumab can give the following side effects:
Headache; fatigue; nausea; upper respiratory tract infection; myalgia .

Summary of study procedures:
- complete or short physical exam (every visit)
- lung function tests (every visit, except screening)
- 1x "airway reversibility test" (screening)
- questionnaires regarding asthma symptoms (every visit)
- blood samples for lab study (every visit)
- urine analysis (every visit)
- pregnancy test (every visit, at screening by serum, thereafter by urine)
- 12-lead ECG (screening)

Contacts

Public
Cephalon Inc

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

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

- The patient is a male or female 12 through 75 years of age with a previous diagnosis of

asthma.
- The patient has an ACQ score of at least 1.5.
- The patient has airway reversibility of at least 12% to beta-agonist administration at screening.
- The patient is currently taking fluticasone at a dosage of at least 440 *g daily (or equivalent).
- The patient has a blood eosinophil count of at least 400/*L.

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 known HES.
- 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 history of use of systemic immunosuppressive or immunomodulating agents (anti-IgE mAb, methotrexate, cyclosporin, interferon-*, or anti-tumor necrosis factor mAb) within 6 months prior to study entry (randomization).
- The patient is currently using systemic corticosteroids (includes use of oral corticosteroids). prior to screening.
- The patient has previously received anti-hIL-5 monoclonal antibody.
- The patient has a current infection or disease that may preclude assessment of asthma.

Study design

Design

Study phase:	3
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):	22-11-2011
Enrollment:	6
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	12-05-2011
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:	24-04-2012
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Not approved Date:	14-01-2013
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-11-2013
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	EUCTR2010-023342-67-NL
ClinicalTrials.gov	NCT01270464
CCMO	NL35307.096.11