201956: A Long-term Access Programme for Subjects with Severe Asthma who Participated in a GSK-sponsored Mepolizumab Clinical Study

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

Summary

ID

NL-OMON43801

Source
ToetsingOnline

Brief title
201956

Condition

- Bronchial disorders (excl neoplasms)

Synonym
severe asthma

Research involving
Human

Sponsors and support

Primary sponsor: GlaxoSmithKline

Source(s) of monetary or material Support: GlaxoSmithKline BV

Intervention

Keyword: Access, Mepolizumab, Programme, Severe asthma

Outcome measures

Primary outcome

NA

Secondary outcome

NA

Study description

Background summary

Mepolizumab is a fully humanized IgG antibody (IgG1, kappa) which binds to and inhibits the ability of
IL-5 to bind to the IL-5 receptor. IL-5 receptors are primarily expressed on eosinophils. IL-5, through
binding to the IL-5 receptor is a major regulator of eosinophils resulting in accumulation in tissues and
modulation of eosinophil behavior at every stage from maturation to survival. Mepolizumab reduces
eosinophils in the periphery and in tissues.
Mepolizumab is being developed for the treatment of a.o. severe astma.
This new protocol (201956) has been designed in order to provide further access to treatment with mepolizumab for subjects with severe asthma who participated in a GSK-sponsored mepolizumab clinical study.
In the Netherlands this applies to subjects from the 200862 study. In this study the efficacy of mepolizumab administered in addition to standard of care in subjects aged 16 years and above diagnosed with an acute exacerbation of asthma has been evaluated.

Study objective

The objective of this protocol is to provide a mechanism to supply mepolizumab on an individual subject basis to eligible asthma subjects who previously participated in a GSK-sponsored mepolizumab study. During the execution of the

protocol SAEs will be collected.

Study design

Long-term Access Programme (LAP) to support provision of open-label mepolizumab on an individual basis to eligible subjects with severe asthma who participated in a clinical study with mepolizumab. Mepolizumab can be initiated within 6 months following the individual subject*s last scheduled visit in the preceding clinical study. Initiation after more than 6 months will be considered on an individual basis by the sponsor.
Treatment: subcutaneously administered mepolizumab at a dose of 100 mg every 4 weeks.
Mepolizumab treatment under this LAP can continue until mepolizumab is commercially licensed for the treatment of asthma in NL or until the sponsor discontinues development in asthma or until the subject meets any of the withdrawal/stopping criteria.

Intervention

Treatment with mepolizumab.

Study burden and risks

Risk: adverse events of mepolizumab.
Burden: subcutaneous injections with mepolizumab every 4 weeks.

Contacts

Public
GlaxoSmithKline

Huis ter Heideweg 61
Zeist 3705 LZ
NL
Scientific
GlaxoSmithKline

Huis ter Heideweg 61
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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Participated in GSK-sponsored asthma clinical study with mepolizumab as specified in the protocol, appendix 2.
• either:
1. completed the treatment period in the mepolizumab asthma clinical study to which they were originally enrolled
or
2. if the subject was withdrawn from study treatment prematurely during the mepolizumab asthma clinical study to which they were originally enrolled but the subject has completed the study assessments at the study visit that would have been the end of the respective treatment period.
• The treating physician considers the benefits of treatment with mepolizumab outweigh the risks for the individual subject.
• Adequate contraception for females of childbearing potential.

Exclusion criteria

• Subject had an adverse event (serious or non-serious) considered related to study treatment whilst participating in a clinical study with mepolizumab which resulted in permanent withdrawal of study treatment.
• Treatment with another biological therapy.
• Treatment with an investigational drug within the past 30 days or 5 terminal phase half-lives.
• Current participation in any other interventional clinical study.
• Pregnancy or breastfeeding

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	mepolizumab
Generic name:	mepolizumab

Ethics review

Approved WMO

Date:	23-07-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	07-09-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	29-01-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-09-2016
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
EudraCT	EUCTR2015-001152-29-NL
CCMO	NL53979.100.15
Other	www.gskclinicalstudyregister.com; registratienummer 201956

Study results