An open-label, single arm, repeat dose, multi-centre study to evaluate the use of a safety syringe for the subcutaneous administration of mepolizumab in subjects with severe eosinophilic asthma (Study 205667)

Published: 08-12-2016
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Primary:To assess the use of mepolizumab in safety syringe for the subcutaneous self-administration of mepolizumab by subjects with severe eosinophilic asthma.Secondary:To assess the use of mepolizumab in safety syringe outside the clinic setting....

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

Summary

ID

NL-OMON45344

Source
ToetsingOnline

Brief title
study 205667

Condition

- Bronchial disorders (excl neoplasms)

Synonym
eosinophilic asthma; asthma

Research involving

Human

Sponsors and support

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

Intervention

Keyword: asthma, mepolizumab, safety, syringe

Outcome measures

Primary outcome

Proportion of subjects successfully able to self-administer their observed

third dose at Week 8.

Secondary outcome

Proportion of subjects successfully able to self-administer their unobserved

second dose outside the

clinic setting at Week 4. Adverse events.

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 eosinophilic asthma and has been registered as add-on treatment for severe refractory eosinophilic asthma in adults.
This new study has been designed to assess the correct real-world use of a

safety syringe for the repeat self-administration of mepolizumab subcutaneously by determining the proportion of subjects with severe eosinophilic asthma who are successfully able to self-administer a dose of mepolizumab.
The formulation of mepolizumab that will be studied in this clinical trial has not yet been administered in a clinical trial. In parallel a PK study in healthy volunteers will be conducted to confirm the comparable PK prophyle with the marketed formulation.

Study objective

Primary:
To assess the use of mepolizumab in safety syringe for the subcutaneous self-administration of mepolizumab by subjects with severe eosinophilic asthma.
Secondary:
To assess the use of mepolizumab in safety syringe outside the clinic setting.
Safety and tolerability of mepolizumab in the safety syringe.

Study design

Open-label, non comparative, repeat-dose, multi-centre study. 3 administrations of mepolizumab 100 mg S.C. every 4 weeks. Treatment period 12 weeks.
1st and 3rd administration in hospital; 2nd administration at home. All administrations by subject or caregiver. Instructions by study staff and reading of user instructions prior to 1st injection. Completion of checklist by subject or caregiver after 2nd injection. Presence of observer (who completes checklist) during 3rd injection.
Follow-up period 4 weeks.
Estimation 75 subjects screened, 55 enrolled.

Intervention

Treatment with mepolizumab.

Study burden and risks

Risk: Adverse events of mepolizumab.
Burden:
5-6 visits in up to 18 weeks.
3 SC injections with mepolizumab (approx. 1 ml).
Physical examination: 2 times.
Blood draws: 5 times (5-15 ml blood).
Pregnancy test: 5 times.
ECG: 2 times.
Completion of checklist after 2nd injection (at home).
Questionnaire about pain at injection site immediately after and 1 and 24 hours after each injection.

Optional genetic blood sample.

Contacts

Public
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705 LZ
NL
Scientific
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705 LZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* 12 years and above (NL: 18 years and above).
* Diagnosis of asthma for *2 years in line with the NIH 2007 guidelines or GINA 2015 guidelines.
* Severe eosinophilic asthma who have been treated with mepolizumab for at least 12 weeks or who have been using high dose inhaled corticosteroids plus an additional controller with a history of 1 or more exacerbations in the last 12 months. See protocol page 25-26 for more details.
* Adequate contraception for females of childbearing potential. See protocol page 26 for details.

Exclusion criteria

* Presence of a known pre-existing, clinically important lung condition other than asthma. See protocol page 27 for details.
* Other conditions that could lead to elevated eosinophils. See protocol page 27 for details.
* Known, pre-existing, unstable liver disease. See protocol page 27 for details.
* A current malignancy or previous history of cancer in remission for less than 12 months. See protocol page 27 for details.
* QTcF prolongation on ECG. See protocol page 27 for details.
* Any monoclonal antibody (including Xolair within 130 days) to treat inflammatory disease within 5 half-lives of Visit 1.
* 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):	05-12-2016
Enrollment:	12
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	08-12-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-02-2017
Application type:	First submission
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	EUCTR2016-001831-10-NL
CCMO	NL59990.100.16
Other	www.gskclinicalstudyregister.com, nummer 205667