A multicenter, randomized, 52-week, double-blind, parallelgroup, active controlled study to compare the efficacy and safety of QVM149 with QMF149 in patients with asthma

Published: 17-12-2015
Last updated: 19-04-2024

The purpose of the trial is to evaluate the efficacy and safety of two different doses of QVM149 (QVM149 150/50/80 *g and QVM149 150/50/160 *g via Concept1) over two respective QMF149 doses (QMF149 150/160 *g and QMF149 150/320 *g via Concept1 in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital respiratory tract disorders
Study type	Interventional

Summary

ID

NL-OMON47663

Source
ToetsingOnline

Brief title
CQVM149B2302

Condition

- Congenital respiratory tract disorders

Synonym
chronic inflammatory disorder of the airways; hyperresponsiveness of the airways

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (sponsor/verrichter van het onderzoek)

Intervention

Keyword: Asthma, Inhalation therapy, QMF149, QVM149

Outcome measures

Primary outcome

The primary objective of this study is to demonstrate superiority of either

QVM149 150/50/80 *g o.d. to QMF149 150/160 *g o.d. or QVM149 150/50/160 *g o.d.

to QMF149 150/320 *g o.d. all delivered via Concept1 in terms of trough FEV1

after 26 weeks of treatment in patients with asthma.

Secondary outcome

The key secondary objective is to demonstrate the superiority of either QVM149

150/50/80 *g o.d. to QMF149 150/160 *g o.d. or QVM149 150/50/160 *g o.d. to

QMF149 150/320 *g o.d., all delivered via Concept1, in terms of ACQ-7 after 26

and 52 weeks of treatment in patients with asthma.

Study description

Background summary

Asthma is a chronic inflammatory disorder of the airways associated with airways hyper responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning. These episodes are usually
associated with widespread but variable airflow obstruction within the lung that is often reversible either spontaneously or with treatment.
Despite existing therapies there is still significant unmet medical needs in asthma, with an estimated 300 million people affected worldwide. The Global

Burden of Asthma Report estimates that 15 million disability*adjusted life years (DALYs) are lost annually due to asthma, representing 1% of the total global burden. Annual worldwide deaths have been estimated at 250,000 (Beasley R, 2004).

Study objective

The purpose of the trial is to evaluate the efficacy and safety of two different doses of QVM149 (QVM149 150/50/80 *g and QVM149 150/50/160 *g via Concept1) over two respective QMF149 doses (QMF149 150/160 *g and QMF149 150/320 *g via Concept1 in poorly controlled asthmatics as determined by pulmonary function testing and effects on asthma control. The primary objective of this study is to demonstrate superiority of either QVM149 150/50/80 *g o.d. to QMF149 150/160 *g o.d. or QVM149 150/50/160 *g o.d. to QMF149 150/320 *g o.d. all delivered via Concept1 in terms of trough FEV1 after 26 weeks of treatment in patients with asthma.

Study design

52 weeks multi-center, randomized, double-blind, double-dummy, parallel-group, active controlled study.

Intervention

The Investigational treatments are as follows:
- QVM149 (indacaterol acetate/ glycopyrronium bromide/MF) 150/50/80 *g o.d. delivered as powder in capsules via Concept1
-QVM149 (indacaterol acetate/glycopyrronium bromide/MF) 150/50/160 *g o.d. delivered as powder in capsules viaConcept1

The Comparative treatments are:
- QMF149 (indacaterol acetate/MF) 150/160 *g o.d. delivered as powder in capsules via Concept1
- QMF149 (indacaterol acetate/MF) 150/320 *g o.d. delivered as powder in capsules via Concept1
- salmeterol xinafoate/fluticasone propionate 50/500 *g b.i.d. delivered as powder via Accuhaler®
In addition the following placebo will be provided to enable the double-dummy design of the study:
- Placebo delivered as powder in capsules via Concept1
Placebo delivered as powder via Accuhaler®

Study burden and risks

Potential burden and risk for participants includes potential side effects of study medication, time investment and additional tests and examinations.See

protocol, Investigator's Brochures, SmPCs and ABR-Form for additional information on risk and benefits.

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

1. Male and female adult patient * 18 years old and * 75 years.
2. Written informed consent must be obtained before any study-related assessment is performed.
3. Patients with a diagnosis of asthma, (GINA 2015 * step 4) for a period of at least 1 year prior to Visit 1 (Screening).
4. Patients who have used medium or high dose ICS/LABA combinations (protocol Appendix 10) for asthma for at least 3 months and at stable medium or high doses of ICS/LABA for at least 1 month prior to Visit 1.

5. Patients must be symptomatic at screening despite treatment with mid or high stable doses
of ICS/LABA. Patients with ACQ-7 score * 1.5 at Visit 101 and at Visit 102 (before randomization) (GINA 2015* step 4). In case that the spiromety is repeated. ACQ-7 should be repeaded as well.
6. Patients with documented history of at least one asthma exacerbation which required medical care from a physician, ER visit (or local equivalent structure) or hospitalization in the 12 months prior to Visit 1 and required systemic corticosteroid treatment.
Previous asthma exacerbation in this context is based on patient*s recall of unplanned need for medical care at any primary care physician, pulmonologist, emergency room or hospital and treatment with systemic corticosteroids due to asthma exacerbation. Investigator must use appropriate means to ensure the accuracy of the patient's exacerbation history (e.g. Patient history at Visit 1 documentend in source notes, pharmacy recored, hospital records, or chart records are acceptable)
7. Pre-bronchodilator FEV1 of < 80 % of the predicted normal value for the patient according to ATS/ERS guidelines after withholding bronchodilators (protocol Table 5-2) at both visits 101 and 102.
8. Patients who demonstrate an increase in FEV1 of 12% and 200 mL within 30 minutes after administration of 400 *g salbutamol/360 *g albuterol (or equivalent dose) at Visit 101.

Exclusion criteria

1. Patients who have smoked or inhaled tobacco products within the 6 month period prior to Visit 1, or who have a smoking history of greater than 10 pack years (Note:1 pack is equivalent to 20 cigarettes. 10 pack years = 1 pack /day x 10 yrs., or * pack/day x 20 yrs.) This includes inhalers such as e-cigarettes at time of Visit 1.
2. Patients who have had an asthma attack/exacerbation requiring systemic steroids or hospitalization or emergency room visit within 6 weeks of Visit 1 (Screening). If patients experience an asthma attack/exacerbation requiring systemic steroids or hospitalization or emergency room visit between Visit 1 and Visit 102 they may be re-screened 6 weeks after recovery from the exacerbation.
3. Patients who have ever required intubation for a severe asthma attack/exacerbation.
4. Patients who have a clinical condition which is likely to be worsened by ICS administration (e.g. glaucoma, cataract and fragility fractures) who are according to investigator*s medical judgment at risk participating in the study.
5. Patients treated with a LAMA for asthma within 3 months prior Visit 1 (Screening).

Study design

Design

Study phase: 3

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2016
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	QMF149
Generic name:	QMF149
Product type:	Medicine
Brand name:	QVM149
Generic name:	QVM149
Product type:	Medicine
Brand name:	Seretide
Generic name:	Salmeterol/fluticasone propionate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	17-12-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	08-02-2016

Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	25-02-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-03-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	04-05-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-10-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	04-11-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-11-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	17-03-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-03-2017

Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-08-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-11-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-01-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-02-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	21-11-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	04-12-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	21-01-2019

Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2015-002899-25-NL
ClinicalTrials.gov	NCT02571777
CCMO	NL55316.075.15