A 52-week treatment, multi-center, randomized, doubleblind, double dummy, parallel-group, active controlled study to compare the effect of QVA149 (indacaterol maleate / glycopyrronium bromide) with salmeterol/fluticasone on the rate of exacerbations in subjects with moderate to very severe COPD (CQVA149A2318)

Published: 30-01-2013
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Primary objective: To demonstrate that QVA149 (110/50 *g o.d.) is at least non-inferior to salmeterol/fluticasone (50/500 *g b.i.d.) in terms of rate of COPD exacerbations.Secondary objectives: Superiority in terms of exacerbation rate. Time to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON41239

Source
ToetsingOnline

Brief title
CQVA149A2318

Condition

- Respiratory disorders NEC

Synonym
COPD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COPD, exacerbation, QVA149, Seretide

Outcome measures

Primary outcome

Exacerbation rate.

Secondary outcome

FEV1, St George questionnaire, rescue medication, COPD symptoms, safety and

tolerability.

Study description

Background summary

Morbidity and mortality due to COPD are increasing. COPD results in a progressive and irreversible decline of the pulmonary function and exacerbations (more symptoms, decreased pulmonary function, decreased quality of life and increased risk for complications), that increase in frequency when the severity of the disease increases.
Anticholinergics and long acting beta2-mimetics belong to the cornerstones of COPD treatment.
QVA149 is a combination of a long acting beta2-agonist (indacaterol) and the anticholinergic drug glycopyrronium bromide.

In this study the effects of QVA149 will be compared to those of Seretide, that is often prescribed in daily practice. Seretide is a combination of the long acting beta2 agonist salmeterol and the inhaled corticosteroid fluticasone. It is administered twice daily.

Study objective

Primary objective: To demonstrate that QVA149 (110/50 *g o.d.) is at least non-inferior to salmeterol/fluticasone (50/500 *g b.i.d.) in terms of rate of COPD exacerbations.
Secondary objectives: Superiority in terms of exacerbation rate. Time to first exacerbation, FEV1, St George questionaire, rescue medication, COPD symptoms, safety and tolerability.

Study design

Randomized double blind, parallel group phase III study. Screening, s.n. adjustment current COPD medication, followed by 4 week run-in period (with titotropium). Thereafter randomisation (1:1) to treatment with:
* QVA149 110/50 mcg o.d.
* Serevent 50/500 mcg twice daily
via dry powder inhaler.
Rescue medication.
Total treatment duration approx. 52 weeks.
Approx. 3000 patients.

Intervention

Treatment with QVA149 or Seretide.

Study burden and risks

Risk: Adverse effects of study medication. Changes in current COPD medication.
Burden: 14 visits in 1 year. Every 2 weeks telephone call. Telephone call 4 weeks after end of treatment.
Daily electronic diary (signs, symptoms, rescue medication). Physical exam 5x, blood tests (safety) 4x (approx. 10 ml blood/visit, total amount 40 ml), pregnancy test 2x, 1x pulmonary function test with reversibility, 7 visits with pulmonary function tests, thereof 6 with 4 tests per visit. 5x ECG (on 3 occasions 2 ECG's). Questionnaires 6x.
Extra tests (not in all centres): 3x collection 24 h urine for cortisol. During 6 visits 4 additional pulmonary function tests (in the 12 h post medication). Completion of extra diary.

Contacts

Public
Novartis

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Male or female adults aged *40 years.
* Patients with stable COPD according to the (GOLD Guidelines, 2011).
* Current or ex-smokers who have a smoking history of at least 10 pack years.
* Post-bronchodilator FEV1 *25% and < 60% of the predicted normal value, and postbronchodilator FEV1/FVC < 0.70.
* At least 1 exacerbation in the previous 12 months.
* Patients taking stable COPD medication (at least 60 days).
* mMRC grade of at least 2.

Exclusion criteria

* Diabetes type I and uncontrolled diabetes type 2.
* History of long QT syndrome or QTc measured at Visit 2 (Fridericia method) is prolonged (>450 ms for males and females).
* Patients who have had a COPD exacerbation in the 6 weeks prior to Visit 1.
* Patients who have had a respiratory tract infection within 4 weeks prior to Visit 1.
* Pregnancy and breast feeding. Inadequate contraception, if relevant.

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):	29-07-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Seretide
Generic name:	salmeterol 50 mcg en fluticasone 500 mcg
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ultibro

Generic name:	QVA149
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-01-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-03-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-05-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-08-2013

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-05-2015
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
Other	Clinicaltrials.gov; NCT01782326
EudraCT	EUCTR2012-004966-16-NL
CCMO	NL43315.060.13