A randomized, double-blind, parallel group, 52-week study evaluating the efficacy, safety and tolerability of NVA237 in patients with poorly controlled asthma (CNVA237B2301)

Published: 30-01-2014
Last updated: 20-04-2024

Primary: To demonstrate the superiority of NVA237 50 *g o.d. compared to placebo in addition to background therapy with long acting B2 agonist/ inhaled corticosteroid (* 800 *g/day of budesonide or equivalent) in terms of trough FEV1 after 26 weeks...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON41186

Source
ToetsingOnline

Brief title
CNVA237B2301

Condition

- Respiratory disorders NEC

Synonym
bronchial asthma; asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: asthma, NVA237, placebo

Outcome measures

Primary outcome

Through level FEV1 after 26 weeks of treatment.

Secondary outcome

Time to 1st moderate to severe asthma exacerbation *definition see protocol

page 50), ACQ-7 at week 26. At week 52: St George questionnaire, asthma quality

of life questionnaire, ACQ-7, 6, 5, trough FEV1 and other pulmonary function

parameters.

Throughout the study: pulmonary function parameters, peakflow at home, asthma

symptoms, rescue medication use, safety and tolerability.

Study description

Background summary

NVA237 is an anti-cholinergic drug, that is being developed as an inhalation powder for the treatment of bronchial asthma for a once daily dosing. The drug has proven safe and effective so far. It has been registered for the indication COPD.
The current phase III study is part of the Development program for asthma.

Study objective

Primary: To demonstrate the superiority of NVA237 50 *g o.d. compared to placebo in addition to background therapy with long acting B2 agonist/ inhaled corticosteroid (* 800 *g/day of budesonide or equivalent) in terms of trough

FEV1 after 26 weeks of treatment.
Secondary: To demonstrate superiority of NVA237 50 *g od compared to placebo in addition to background therapy with long acting B2 agonist/ inhaled corticosteroid (* 800 *g/day of budesonide or equivalent) for time to 1st moderate to severe asthma exacerbation and ACQ-7 at week 26.
To compare the efficacy of NVA237 50 mcg od compared to placebo in terms of health outcome questionnaires, pulmonary function parameters, peak flow, asthma symptoms, rescue medication, safety and tolerability.

Study design

Multicenter gerandomiseerd dubbelblind fase III onderzoek met parallelle groepen. Washout of prohibited medication. Run-in period on LABA/ ICS (* 800 *g/ day of budesonide or equivalent) Thereafter randomization (1:1) to treatment with:
3. NVA237 50 mcg od
4. Placebo
during 52 weeks in a single dose dry powder inhaler.
Background medication long acting B2 agonist/ inhaled corticosteroid (* 800 *g/ day of budesonide or equivalent).
Salbutamol rescue medication.
Treatment duration 56 weeks.
Approx1938 patients.

Intervention

Treatment with NVA237 or placebo.

Study burden and risks

Risk: Adverse effects of study medication. Discontinuation of prohibited medication.
Burden: 10 visits (4 with an additional blood draw the next morning) plus 1 final telephone call. Duration 1-4 hours.
Physical examination 5 x.
Safety blood tests 4 x (8 ml); fasting.
Pregnancy test 3 x.
Pulmonary function test plus reversibility 1 x.
Serial pulmonary function tests during all visits of treatment period; 4 visits 9 tests (incl. trough values next morning); 4 visits 2 tests.
ECG 5 x.
Questionnaires (St George questionnaire, asthma symptom questionnaire, asthma quality of life questionnaire) 4 x.
Diary (asthma symptoms, rescue medication) and peak flow twice daily during run-in and treatment period.

Optional: pharmacogenetic research; 1 blood sample of 10 ml.

Contacts

Public
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL
Scientific
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Male and female adult patients aged 18-75 years.
* Diagnosis of asthma (according to GINA 2012) for a period of at least 5 years prior screening and prior to the age of 40.
* Increase in FEV1 of * 12% and * 200 mLs within 30 minutes after administration of 400 *g salbutamol (or equivalent dose).
* Pre-bronchodilator FEV1 of * 50 and * 80% of predicted.
* Stable dose of a fixed dose ICS and LABA combination for at least 4 weeks prior to screening. Total daily dose of ICS of * 800 *g/day of budesonide or equivalent.
* Symptomatic with a mean ACQ-5 score * 1.5 at Visit 101 and Visit 102.

* A documented history of one or more asthma exacerbations in the previous 12 months. See protocol page 22 for details.

Exclusion criteria

* ECG abnormalities. See protocol page 23 for details.
* Prohibited medications. See protocol page 30-31 for details.
* Pregnancy, lactation.
* Females of childbearing potential not using adequate contraception. See protocol page 23 for details.
* Type 1 or 2 uncontrolled diabetes.
* BMI of more than 40 kg/m2.
* Asthma exacerbation in the 6 weeks prior to screening. See protocol page 24 items 13-14 for details.
* Respiratory tract infection in the 4 weeks prior to screening. See protocol page 24 items 15-16 for details.
* Smoking in the past 6 months or smoking history of more than 10 pack years.

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:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Seebri
Generic name:	glycopyrronium bromide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	30-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-03-2014
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
Other	clinicaltrials.gov; registratienummer n.n.b.
EudraCT	EUCTR2013-002664-10-NL
CCMO	NL47756.060.14