A 52-week treatment, multicenter, randomized, doubleblind, double dummy, placebo-controlled, parallel-group study to assess the efficacy, safety and tolerability of indacaterol (300 & 600 µg o.d.) in patients with chronic obstructive pulmonary disease, using formoterol (12 µg b.i.d.) as an active control

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To assess indacaterol (300 and 600 ug once daily via SDDPI) superiority in patients with COPD as compared to placebo with respect to 24 h post dose (through) FEV1 after 12 weeks of treatment.

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

Summary

ID

NL-OMON30259

Source
ToetsingOnline

Brief title
Indacaterol COPD study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Het onderzoek wordt gefinancieerd door de opdrachtgever Novartis Pharma B.V.

Intervention

Keyword: COPD, Indacaterol, Placebo-controlled, QAB149

Outcome measures

Primary outcome

24 hrs post dose FEV1 after 12 weeks

Secondary outcome

Safety and tolerability: vital signs, ECG, laboratory results, adverse events

and co-medication/significant non-medical therapies.

Efficacy: Spirometry (FEV1), questionnaires, walking test, diary data

Pharmacokinetic data.

Study description

Background summary

Indacaterol is a novel, long-acting B2-adrenerg receptor agonist, meant for once daily treatment in patients with COPD and/or asthma.

Study objective

To assess indacaterol (300 and 600 ug once daily via SDDPI) superiority in patients with COPD as compared to placebo with respect to 24 h post dose (through) FEV1 after 12 weeks of treatment.

Study design

The study is a multi-center, double-blind, double dummy, parallel group study.

During the pre-screen visit, the informed consent is obtained and current COPD medications are reviewed and if necessary arrangements are made to adjust prohibited COPD therapy to allowable COPD therapy.
At the screening visits (V1 and V2) eligibility is being assessed to protocol criteria. The period between V1/V2 and V3 (14 days) is called the run-in period and is used to assess further eligibility for the study and to collect baseline diary data.
V3 to V17 is a treatment period of 52 weeks in which the patients are being treated with either indacaterol 300 or 600 ug once daily, formoterol 12 ug twice daily or placebo (1:1:1:1)
In a sub-group of patients, 12 h spirometry will be performed at V3, V8 en V16 (day 1, after 12 weeks and after 52 weeks of treatment).
The patient is allowed to use his/her inhaled corticosteroids during the study and is allowed to use salbutamol as rescue medication.

Intervention

Indacaterol 300 ug group: morning: 1 x 300 ug indacaterol, 1 x indacaterol placebo and 1x formoterol placebo, evening 1 x formoterol placebo
Indacaterol 300 ug group: morning 2 x 300 ug indacaterol, 1 x formoterol placebo, evening 1 x formoterol placebo
Formoterol group: morning 1 x 12 ug formoterol, 2 x incadaterol placebo, evening 1 x 12 ug formoterol
Placebo group: morning 2 x indacaterol placebo, 1 x formoterol placebo, evening 1 x formoterol placebo

Study burden and risks

Burden:
Intake of study medication (52 weeks and double dummy), daily completion of diary and peak flow two times a day, 17 x visit to the clinic in 54 weeks, 4 x physical examination, 19 x vital signs, 36 x ECG, 6 x urine collection, 51 x spirometry, 13 x blood draw, 7 x completion of questionnaires, 3 x walking test.

Risk:
So far, when using indacaterol, the same side effects have been seen as

compared to other bronchodilators, such as: tremor (shaking), headache, palpitations, muscle cramps and nausea.
These side effects were most of the time mild and went over when time passed by, they seldom needed treatment. Just like in every other clinical research study, the use of study medication can be related to unexpected events or side effects.
The risks of taking blood is not different then normal and may include pain and/or bruising.

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 adults aged >= 40 years
2. Outpatients with a diagnosis of COPD according to the GOLD Guidelines (2005) and:

a) Smoking history of at least 20 pack years
b) Pre-bronchodilator FEV1 < 65% of the predicted normal value and at least 0.75 L.
c) Pre-bronchodilator FEV1/FVC < 70%

Exclusion criteria

1. Pregnant or nursing (lactating) women
2. Women of child-bearing potential unless they are postmenopausal, had surgical sterilization, use hormonal contraception or double-barrier methods
3. Patients who have been hospitalized for a COPD exacerbation in the 6 weeks prior to Visit 1 or during the run-in period
4. Patients requiring long term (> 6 months) oxygen therapy for chronic hypoxemia
5. Patients who have had a respiratory tract infection within 6 weeks prior to Visit 1.
6. Patients with concomitant pulmonary disease, pulmonary tuberculosis (unless confirmed by chest x-ray to be no longer active) or clinically significant bronchiectasis
7. Patients with a history (up to and including Visit 1) of asthma indicated by (but not limited to):
a) Blood eosinophil count > 400/mm3
b) Onset of respiratory symptoms prior to age 40 years
8. Patients with diabetes Type I or uncontrolled diabetes Type II i(HbA1c > 8.0% of total Hb measured at Visit 1)
9. Any patient with lung cancer or a history of lung cancer
10. Any patient with active cancer or a history of cancer with less than 5 years disease free survival time. Localized basal cell carcinoma (without metastases) of the skin is acceptable.
11. Patients with a history of long QT syndrome or whose QTc interval (Bazett*s) is prolonged to > 450 ms (males) or > 470 ms (females)
12. Patients who have had live attenuated vaccinations within 30 days prior to Visit 1 or during the run-in period. (Inactivated influenza vaccination, pneumococcal vaccination or any other inactivated vaccine is acceptable provided it is not administered within 48 h prior to Visits 1, 2 or 3)
13. Treatments for COPD and allied conditions: the following medications must not be used prior to Visit 1 for at least the minimum washout period specified below or at any time during the study:
a) The long acting anti-cholinergic agent tiotropium: 7 days
b) Short acting anti-cholinergics: 8 h
c) Fixed combinations of β2-agonists and inhaled corticosteroids: 48 h
(Patients taking fixed dose combination therapy must be switched to the equivalent inhaled corticosteroid as monotherapy plus salbutamol/albuterol as rescue therapy)
d) Fixed combinations of β2-agonists and inhaled anticholinergics: 48 h
e) Long-acting β2-agonists: 48 h
f) Short acting β2-agonists (other than those prescribed in the study): 6 h
g) Theophylline and other xanthines: 1 week
h) Parenteral or oral corticosteroids: 1 month
14. Treatments for COPD and allied conditions: The following medications should not be used unless they have been stabilized:

a) Cromoglycate, nedocromil, ketotifen, omalizumab, inhaled or nasal corticosteroids and leukotriene antagonists - at least one month prior to Visit 1
b) Antihistamines (excluding those in 19c below) - at least 5 days prior to Visit 1
15. Other excluded medications:
a) Non-potassium sparing diuretics (unless administered as a fixed dose combination with a potassium conserving drug)
b) Non-selective beta-blocking agents
c) Cardiac anti-arrhythmics Class Ia (e.g., disopyramide, procainamide, quinidine), Class III (e.g., amiodarone, dofetilide, ibutilide, sotalol), terfenadine, astemizole, mizolastin and any drug with potential to significantly prolong the QT interval
d) Tricyclic antidepressants and monoamino-oxidase inhibitors.
16. Patients unable to successfully use a dry powder inhaler device or perform spirometry measurements

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:	Recruitment stopped
Start date (anticipated):	30-10-2006
Enrollment:	96
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Foradil

Generic name:	Formoterol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	nog niet geregistreerd voor deze indicatie
Generic name:	Indacaterol

Ethics review

Approved WMO Date:	28-09-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-01-2007
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	EUCTR2006-001954-28-NL
CCMO	NL14017.060.06