A phase III, randomized, double-blind, double-dummy, placebo-controlled, multicenter, 3-period incomplete block, multidose crossover study to determine the effect on lung function of indacaterol (150 and 300 mcg o.d.) in patients with moderate to severe COPD, using tiotropium (18 mcg o.d.) as an active control

Published: 03-12-2007
Last updated: 11-05-2024

The study is designed to compare the 24-h spirometry profile of two doses of indacaterol (150o.d. and 300 *g o.d.) with that of placebo (o.d.) and with tiotropium (18 *g o.d.) as an activecontrol in patients with COPD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON32333

Source
ToetsingOnline

Brief title
CQAB149B2331

Condition

- Respiratory tract infections

Synonym
COPD, lungemphysema

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: de industie zoals opgegeven bij B6

Intervention

Keyword: COPD, Cross over Design, QAB149B2331, Tiotropium

Outcome measures

Primary outcome

To determine if indacaterol (150 *g o.d. and/or 300 *g o.d.) is superior to

placebo in terms of

24 h post dose trough FEV1 after 14 days of treatment in each treatment period

in patients

with COPD.

Secondary outcome

To determine if indacaterol (150*g o.d. and/or 300*g o.d.) are at least

non-inferior to

tiotropium 18*g o.d. in terms of 24 h post dose trough FEV1 after 14 days of

treatment in

each treatment period in patients with COPD.

To evaluate the effects of indacaterol (150 o.d. and 300 *g o.d.) and

tiotropium (18 *g o.d.) in

terms of peak effect and time to peak effect level as determined by FEV1 on Day

1 of

treatment in each treatment period.

To evaluate the area under the FEV1 time curves (0-24 h) on Day 1 and Day 14 in

each

treatment period

To evaluate the effects of indacaterol and tiotropium in terms of 24 h

post-dose trough FEV1

after 1 day of treatment in each treatment period.

Treatment comparison will be made for FEV1 at each scheduled time point in each

treatment

period.

To evaluate the safety of indacaterol in terms of vital signs, glucose and

potassium, ECG and

adverse events.

Study description

Background summary

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

Study objective

The study is designed to compare the 24-h spirometry profile of two doses of indacaterol (150
o.d. and 300 *g o.d.) with that of placebo (o.d.) and with tiotropium (18 *g

o.d.) as an active
control in patients with COPD.

Study design

A phase III, randomized, double-blind, double-dummy, placebo-controlled, multicenter, 3-period incomplete block, multidose crossover study to determine the effect on lung function of indacaterol (150 and 300 mcg o.d.) in patients with moderate to severe COPD, using tiotropium (18 mcg o.d.) as an active control

During the pre screen visit (vo) 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 2) eligibility is being assessed to protocol criteria. The period betrween v1/v2 and V3 (14 days) is called the run in (screeningperiod) and is used to assess further eligibility for the study and to collect baslin diary data.

At the baseline visit (v3) patients whose eligibility is confirmed will be randomized to one of the available treatment sequences in this 3 period cross over design. Patient will then enter the first of the 3 double blind 14 days treatment period. Patients will be assessed on consecutive days at the beginning and end of each treatment period (the first and second and the 14th and 15th day). On the first and 14the day the patietns will be required to remain at the study center until 14 hours after taking study medication. Patients will then return on the next day to complete the 23h10,23h45 and 23u55 post dose spirometry.
In total the patients will be required to visit the study centre 14 times (excl V0). In between the treatment period there is a wash out period of also 14 days.
During the study patients will be permitted to use allowable COPD mediation described in section 5.1 of the protocol and will be provided with a salbutamol inhaler to use as rescuemedication.

Intervention

Indacaterol 150mcg
Indacaterol 300mcg
Tiotropium 18mcg
Placebo

salbutamol as rescuemedication

Study burden and risks

It cannot be guaranteed that the health of each individual patient will improve by participating in this study. Patients will be checked up regularly during this study and medication will be provided at no costs.
The results of this study might help other patients with COPD.

Burden;
2 questionnaires to be completed at V3, 2 times Physical examination, once reversibility testing, on 14 visits spirometry, at 13 visits blood sampling and on 8 visits multiple ECGs will be made

In addition to the standard blood draws, there will be PK blood draws. In total (standard plus PK), 314 ml blood will be drawn.

Possible side effects of indacaterol can include: tremor, headache, coubh, palpitations, muscle cramps, nausia, chest pain, trouble sleeping, nervousness, dry mouth, dizziness, tiredness, felling generallty unwell and possible changes in blood pressure or potassium or blood sugar.

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 patients aged 40 years and older
* Patients with moderate to severe stable COPD according to the COLD Guidelines 2006
* Patients with a smoking history of at least 10 pack years
* Patients with a post-brochodilator FEV1 equal or greater than 30% of the predicted normal value and less than 80% of the predicted normal value, and post bronchodilator FEV1/FVC less than 0.7

Exclusion criteria

* Patients who have been hospitalized for a COPD exacerbation in the 6 weeks prior to Visit 1 or during the run-in period
* Patients requiring long term oxygen therapy
* Patients who have had a respiratory tact infection within 6 weeks prior to V1
* Patients with a history of Asthma
* Patients with diabetes Type 1 and uncontrolled diabetes type II
* Patients with a hostory of long QT syndrome or whose QTc interval measured at visti 1 or 3 is prolonged

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2008
Enrollment:	26
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nog niet bekend
Generic name:	Indacaterol
Product type:	Medicine
Brand name:	Spiriva
Generic name:	Tiotropium
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-12-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-01-2008
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	EUCTR2007-004071-19-NL
CCMO	NL20571.060.07