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Trial record **1 of 1** for: CQAB149B2307

Previous Study | Return to List | Next Study

Study to Determine the Onset of Action of Indacaterol in Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00669617

First received: April 28, 2008
Last updated: September 7, 2011
Last verified: September 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
	Drug: Indacaterol Drug: Salmeterol/fluticasone (50/500 µg)

Interventions:	Drug: Salbutamol (200 µg) Drug: Placebo to Indacaterol Drug: Placebo to Salmeterol/fluticasone Drug: Placebo to salbutamol

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Ind 150µg, Salm/Flut, Ind 300µg, Placebo, Salbut	Participants received a single dose of each treatment from Period I - V in the following order, separated by a washout period of 4-7 days: Indacaterol 150 µg (Ind 150µg), Salmeterol/fluticasone 50/500 µg (Salm/flut), Indacaterol 300 µg (Ind 300µg), Placebo, Salbutamol 200 µg (Salbut). At each treatment visit, participants received the specified treatment and 2 placebo inhalations (one inhalation from the SDDPI, and one inhalation from each of the two MDDPIs) to maintain blinding. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Ind 300µg, Ind 150µg, Salbut, Salm/Flut, Placebo	Participants received a single dose of each treatment from Period I - V in the following order, separated by a washout period of 4-7 days: Indacaterol 300 µg (Ind 300µg), Indacaterol 150 µg (Ind 150µg), Salbutamol 200 µg (Salbut), Salmeterol/fluticasone 50/500 µg (Salm/flut), Placebo. At each treatment visit, participants received the specified treatment and 2 placebo inhalations (one inhalation from the SDDPI, and one inhalation

	from each of the two MDDPIs) to maintain blinding. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Salm/Flut, Placebo, Ind 150µg, Salbut, Ind 300µg	Participants received a single dose of each treatment from Period I - V in the following order, separated by a washout period of 4-7 days: Salmeterol/fluticasone 50/500 µg (Salm/flut), Placebo, Indacaterol 150 µg (Ind 150µg), Salbutamol 200 µg (Salbut), Indacaterol 300 µg (Ind 300µg). At each treatment visit, participants received the specified treatment and 2 placebo inhalations (one inhalation from the SDDPI, and one inhalation from each of the two MDDPIs) to maintain blinding. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Salbut, Ind 300µg, Placebo, Ind 150µg, Salm/Flut	Participants received a single dose of each treatment from Period I - V in the following order, separated by a washout period of 4-7 days: Salbutamol 200 µg (Salbut), Indacaterol 300 µg (Ind 300µg), Placebo, Indacaterol 150 µg (Ind 150µg), Salmeterol/fluticasone 50/500 µg (Salm/flut). At each treatment visit, participants received the specified treatment and 2 placebo inhalations (one inhalation from the SDDPI, and one inhalation from each of the two MDDPIs) to maintain blinding. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo, Salbut, Salm/Flut , Ind 300µg, Ind 150µg	Participants received a single dose of each treatment from Period I - V in the following order, separated by a washout period of 4-7 days: Placebo, Salbutamol 200 µg (Salbut), Salmeterol/fluticasone 50/500 µg (Salm/Flut), Indacaterol 300 µg (Ind 300µg), Indacaterol 150 µg (Ind 150µg). At each treatment visit, participants received the specified treatment and 2 placebo inhalations (one inhalation from the SDDPI, and one inhalation from each of the two MDDPIs) to maintain blinding. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Participant Flow for 5 periods

Period 1: Period 1

	Ind 150µg, Salm/Flut, Ind 300µg, Placebo, Salbut	Ind 300µg, Ind 150µg, Salbut, Salm/Flut, Placebo	Salm/Flut, Placebo, Ind 150µg, Salbut, Ind 300µg	Salbut, Ind 300µg, Placebo, Ind 150µg, Salm/Flut	Placebo, Salbut, Salm/Flut , Ind 300µg, Ind 150µg

STARTED	**18**	**17**	**18**	**18**	**18**
COMPLETED	**18**	**17**	**17**	**18**	**17**
NOT COMPLETED	**0**	**0**	**1**	**0**	**1**
Withdrawal by Subject	**0**	**0**	**1**	**0**	**0**
Protocol Deviation	**0**	**0**	**0**	**0**	**1**

Period 2: Period 2

	Ind 150µg, Salm/Flut, Ind 300µg, Placebo, Salbut	Ind 300µg, Ind 150µg, Salbut, Salm/Flut, Placebo	Salm/Flut, Placebo, Ind 150µg, Salbut, Ind 300µg	Salbut, Ind 300µg, Placebo, Ind 150µg, Salm/Flut	Placebo, Salbut, Salm/Flut , Ind 300µg, Ind 150µg
STARTED	**18**	**17**	**17**	**18**	**17**
COMPLETED	**18**	**17**	**17**	**18**	**17**
NOT COMPLETED	**0**	**0**	**0**	**0**	**0**

Period 3: Period 3

	Ind 150µg, Salm/Flut, Ind 300µg, Placebo, Salbut	Ind 300µg, Ind 150µg, Salbut, Salm/Flut, Placebo	Salm/Flut, Placebo, Ind 150µg, Salbut, Ind 300µg	Salbut, Ind 300µg, Placebo, Ind 150µg, Salm/Flut	Placebo, Salbut, Salm/Flut , Ind 300µg, Ind 150µg
STARTED	**18**	**17**	**17**	**18**	**17**
COMPLETED	**17**	**17**	**17**	**18**	**17**

NOT COMPLETED	**1**	**0**	**0**	**0**	**0**
Lost to Follow-up	**1**	**0**	**0**	**0**	**0**

Period 4: Period 4

	Ind 150µg, Salm/Flut, Ind 300µg, Placebo, Salbut	Ind 300µg, Ind 150µg, Salbut, Salm/Flut, Placebo	Salm/Flut, Placebo, Ind 150µg, Salbut, Ind 300µg	Salbut, Ind 300µg, Placebo, Ind 150µg, Salm/Flut	Placebo, Salbut, Salm/Flut , Ind 300µg, Ind 150µg
STARTED	**17**	**17**	**17**	**18**	**17**
COMPLETED	**17**	**17**	**17**	**18**	**17**
NOT COMPLETED	**0**	**0**	**0**	**0**	**0**

Period 5: Period 5

	Ind 150µg, Salm/Flut, Ind 300µg, Placebo, Salbut	Ind 300µg, Ind 150µg, Salbut, Salm/Flut, Placebo	Salm/Flut, Placebo, Ind 150µg, Salbut, Ind 300µg	Salbut, Ind 300µg, Placebo, Ind 150µg, Salm/Flut	Placebo, Salbut, Salm/Flut , Ind 300µg, Ind 150µg
STARTED	**17**	**17**	**17**	**18**	**17**
COMPLETED	**17**	**17**	**17**	**18**	**17**
NOT COMPLETED	**0**	**0**	**0**	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Total Population	Participants were randomized to one of five treatment sequences. Each treatment sequence comprised 5 double-blind, single dose treatment periods (Periods I to V), separated by a washout period of 4-7 days. Participants received each of the 5 blinded-treatments: indacaterol 150 µg, indacaterol 300 µg, salmeterol/fluticasone 50/500 µg, salbutamol 200 µg and placebo.

Baseline Measures

	Total Population
Number of Participants [units: participants]	**89**
Age [units: years] Mean (Standard Deviation)	**62.3 (8.37)**
Gender [units: participants]	
Female	**35**
Male	**54**

Outcome Measures

1. Primary: Forced Expiratory Volume in 1 Second (FEV1) at 5 Minutes Post-dose [Time Frame: Five Minutes Post Dose]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) at 5 Minutes Post-dose
Measure Description	FEV1 was measured at 5 minutes after dosing with spirometry conducted according to internationally accepted standards. The time of dosing was defined as the time corresponding to the use of the first inhaler device. The primary variable was analyzed using a mixed model containing the period baseline FEV1 as covariate. The period baseline FEV1 was the average of the FEV1 value measured in the clinic at 50 and 15 min prior to the study drug administration in that period.
Time Frame	Five Minutes Post Dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Modified Intent-to-Treat (mITT) population: including all randomized patients who received at least one dose of study drug. If any of the values used in the period baseline FEV1 and FEV1 at 5 min post-dose were collected within 6 hours of rescue medication, then the individual FEV1 value was set to missing.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received a single dose of Indacaterol 150 µg delivered via a Single-Dose Dry-Powder Inhaler (SDDPI), placebo to salmeterol/fluticasone delivered via Multi-Dose Dry-Powder Inhaler (MDDPI) and placebo to salbutamol delivered via MDDPI. Each treatment period lasted up to 2 hours following study drug administration and was separated from the previous treatment by a washout period of 4 to 7 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Indacaterol 300 µg	Participants received a single dose of Indacaterol 300 µg delivered via a Single-Dose Dry-Powder Inhaler (SDDPI), a placebo to salmeterol/fluticasone delivered via Multi-Dose Dry-Powder Inhaler (MDDPI) and a placebo to salbutamol delivered via MDDPI. Each treatment period lasted up to 2 hours following study drug administration and was separated from the previous treatment by a washout period of 4 to 7 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Participants received placebo to indacaterol delivered via Single-Dose Dry-Powder Inhaler (SDDPI), a placebo to salmeterol/fluticasone delivered via Multi-Dose Dry-Powder (MDDPI) and placebo to salbutamol delivered via MDDPI. Each treatment period lasted up to 2 hours following study drug administration and was separated from the previous one by a washout period of 4 to 7 days. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol/Fluticasone	Participants received a single dose of Salmeterol/fluticasone 50/500 µg delivered via MDDPI, a placebo to indacaterol delivered via SDDPI and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Salbutamol	Participants received a single dose of Salbutamol 200 µg delivered via MDDPI, a placebo to indacaterol delivered via SDDPI and placebo to salmeterol/fluticasone delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Indacaterol 300 µg	Placebo	Salmeterol/Fluticasone	Salbutamol
Number of Participants Analyzed [units: participants]	**85**	**87**	**88**	**88**	**86**
Forced Expiratory Volume in 1 Second (FEV1) at 5 Minutes Post-dose [units: Liters] Least Squares Mean (Standard Error)	**1.48 (0.014)**	**1.50 (0.014)**	**1.38 (0.014)**	**1.43 (0.014)**	**1.47 (0.014)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) at 5 Minutes Post-dose

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	54 days
Additional Description	Safety population including all patients who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received a single dose of Indacaterol 150 µg delivered via a Single-Dose Dry-Powder Inhaler (SDDPI), placebo to salmeterol/fluticasone delivered via Multi-Dose Dry-Powder Inhaler (MDDPI) and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Participants received a single dose of Indacaterol 300 µg delivered via Single-Dose Dry-Powder Inhaler (SDDPI), a placebo to salmeterol/fluticasone delivered via Multi-Dose Dry-Powder Inhaler (MDDPI) and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Salbutamol	Participants received a single dose of Salbutamol 200 µg delivered via MDDPI, a placebo to indacaterol delivered via SDDPI and placebo to salmeterol/fluticasone delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol/Fluticasone	Participants received a single dose of Salmeterol/fluticasone 50/500 µg delivered via MDDPI, a placebo to indacaterol delivered via SDDPI and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Participants received placebo to indacaterol delivered via SDDPI, a placebo to salmeterol/fluticasone delivered via MDDPI and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Serious Adverse Events

	Indacaterol 150 µg	Indacaterol 300 µg	Salbutamol	Salmeterol/Fluticasone	Placebo
Total, serious adverse events					
# participants affected / at risk	**0/86 (0.00%)**	**0/87 (0.00%)**	**0/86 (0.00%)**	**0/88 (0.00%)**	**0/87 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	54 days
Additional Description	Safety population including all patients who received at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 150 µg	Participants received a single dose of Indacaterol 150 µg delivered via a Single-Dose Dry-Powder Inhaler (SDDPI), placebo to salmeterol/fluticasone delivered via Multi-Dose Dry-Powder Inhaler (MDDPI) and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Indacaterol 300 µg	Participants received a single dose of Indacaterol 300 µg delivered via Single-Dose Dry-Powder Inhaler (SDDPI), a placebo to salmeterol/fluticasone delivered via Multi-Dose Dry-Powder Inhaler (MDDPI) and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Salbutamol	Participants received a single dose of Salbutamol 200 µg delivered via MDDPI, a placebo to indacaterol delivered via SDDPI and placebo to salmeterol/fluticasone delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol/Fluticasone	Participants received a single dose of Salmeterol/fluticasone 50/500 µg delivered via MDDPI, a placebo to indacaterol delivered via SDDPI and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Participants received placebo to indacaterol delivered via SDDPI, a placebo to salmeterol/fluticasone delivered via MDDPI and placebo to salbutamol delivered via MDDPI. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Other Adverse Events

	Indacaterol 150 µg	Indacaterol 300 µg	Salbutamol	Salmeterol/Fluticasone	Placebo
Total, other (not including serious) adverse events					
# participants affected / at risk	**0/86 (0.00%)**	**0/87 (0.00%)**	**0/86 (0.00%)**	**0/88 (0.00%)**	**0/87 (0.00%)**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party: External Affairs, Novartis
ClinicalTrials.gov Identifier: NCT00669617 History of Changes

Other Study ID Numbers:	**CQAB149B2307** EUDRACT: 2007-006189-14
Study First Received:	April 28, 2008
Results First Received:	July 22, 2011
Last Updated:	September 7, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy United States: Food and Drug Administration