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Trial record **1 of 1** for: CQAB149B2346

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Efficacy and Safety of Indacaterol in Patients With Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00624286

First received: February 15, 2008
Last updated: July 22, 2011
Last verified: July 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: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: Indacaterol 150 µg Drug: Placebo to indacaterol

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
Indacaterol 150 µg	Patients inhaled indacaterol 150 µg once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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 to Indacaterol	Patients inhaled placebo to indacaterol once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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: Overall Study

	Indacaterol 150 µg	Placebo to Indacaterol
STARTED	**211**	**205**
COMPLETED	**186**	**178**
NOT COMPLETED	**25**	**27**
Protocol Deviation	**7**	**9**

Adverse Event	**6**	**3**
Withdrawal by Subject	**5**	**4**
Lost to Follow-up	**3**	**2**
Administrative problems	**3**	**0**
Lack of Efficacy	**1**	**6**
Not stated	**0**	**1**
Abnormal test procedure result(s)	**0**	**1**
Death	**0**	**1**

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
Indacaterol 150 µg	Patients inhaled indacaterol 150 µg once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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 to Indacaterol	Patients inhaled placebo to indacaterol once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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.

Total	Total of all reporting groups

Baseline Measures

	Indacaterol 150 µg	Placebo to Indacaterol	Total
Number of Participants [units: participants]	**211**	**205**	**416**
Age [units: years] Mean (Standard Deviation)	**62.9 (9.89)**	**63.2 (9.62)**	**63.0 (9.75)**
Gender [units: participants]			
Female	**103**	**95**	**198**
Male	**108**	**110**	**218**

Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of the Study (Week 12 + 1 Day, Day 85) [Time Frame: 24 hours post-dose at the end of the study (Week 12 + 1 day, Day 85)]

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of the Study (Week 12 + 1 Day, Day 85)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. Trough FEV1 was defined as the average of measurements made 23 hours 10 minutes and 23 hours 45 minutes post-dose at the end of treatment. The analysis included baseline FEV1, FEV1 pre-dose and 30 minutes post-dose of salbutamol during screening, and FEV1 pre-dose and 1 hour post-dose of ipratropium during screening as covariates.

Time Frame	24 hours post-dose at the end of the study (Week 12 + 1 day, Day 85)
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.
Intent-to-treat population: All randomized patients who received at least 1 dose of study drug, last observation carried forward (LOCF).

Reporting Groups

	Description
Indacaterol 150 µg	Patients inhaled indacaterol 150 µg once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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 to Indacaterol	Patients inhaled placebo to indacaterol once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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	**Placebo to Indacaterol**
Number of Participants Analyzed **[units: participants]**	**201**	**189**
Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of the Study (Week 12 + 1 Day, Day 85) **[units: Liters]** **Least Squares Mean (Standard Error)**	**1.48 (0.018)**	**1.35 (0.019)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of the Study (Week 12 + 1

Day, Day 85)

2. Secondary: Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 2 [Time Frame: 24 hours post-dose on Day 2]

Measure Type	Secondary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 2
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. Trough FEV1 was defined as the average of measurements made 23 hours 10 minutes and 23 hours 45 minutes post-dose at the end of treatment. The analysis included baseline FEV1, FEV1 pre-dose and 30 minutes post-dose of salbutamol during screening, and FEV1 pre-dose and 1 hour post-dose of ipratropium during screening as covariates.
Time Frame	24 hours post-dose on Day 2
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.
Intent-to-treat population: All randomized patients who received at least 1 dose of study drug. FEV1 data taken within 6 h of rescue medication was excluded from this analysis.

Reporting Groups

	Description
Indacaterol 150 µg	Patients inhaled indacaterol 150 µg once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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 to Indacaterol	Patients inhaled placebo to indacaterol once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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	Placebo to Indacaterol
Number of Participants Analyzed [units: participants]	**205**	**197**
Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 2 [units: Liters] Least Squares Mean (Standard Error)	**1.47 (0.014)**	**1.38 (0.014)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose on Day 2

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	12 weeks
Additional Description	Safety population included all patients who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol 150 µg	Patients inhaled indacaterol 150 µg once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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 to Indacaterol	Patients inhaled placebo to indacaterol once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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	Placebo to Indacaterol
Total, serious adverse events		
# participants affected / at risk	**7/211 (3.32%)**	**5/205 (2.44%)**
Cardiac disorders		
Acute myocardial infarction † [1]		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**
Myocardial infarction † [1]		
# participants affected / at risk	**0/211 (0.00%)**	**1/205 (0.49%)**
Gastrointestinal disorders		
Pancreatitis acute † [1]		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**
Peptic ulcer † [1]		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**
General disorders		
Death † [1]		
# participants affected / at risk	**0/211 (0.00%)**	**1/205 (0.49%)**
Hepatobiliary disorders		
Cholelithiasis † [1]		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**
Infections and infestations		
Staphylococcal infection † [1]		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**

Injury, poisoning and procedural complications		
Exposure to toxic agent † 1		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**
Lower limb fracture † 1		
# participants affected / at risk	**0/211 (0.00%)**	**1/205 (0.49%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Lung neoplasm malignant † 1		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**0/211 (0.00%)**	**2/205 (0.98%)**
Vascular disorders		
Haematoma † 1		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**
Vascular pseudoaneurysm † 1		
# participants affected / at risk	**1/211 (0.47%)**	**0/205 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	12 weeks

Additional Description	Safety population included 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	Patients inhaled indacaterol 150 µg once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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 to Indacaterol	Patients inhaled placebo to indacaterol once daily in the morning between 8:00 AM and 11:00 AM via a single-dose dry-powder inhaler (SDDPI) for 12 weeks. 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	Placebo to Indacaterol
Total, other (not including serious) adverse events		
# participants affected / at risk	**30/211 (14.22%)**	**37/205 (18.05%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**18/211 (8.53%)**	**24/205 (11.71%)**
Cough † 1		
# participants affected / at risk	**13/211 (6.16%)**	**15/205 (7.32%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

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 (ie, 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 by Novartis

Publications automatically indexed to this study:

Jones PW, Donohue JF, Nedelman J, Pascoe S, Pinault G, Lassen C. Correlating changes in lung function with patient outcomes in chronic obstructive pulmonary disease: a pooled analysis. Respir Res. 2011 Dec 29;12:161. doi: 10.1186/1465-9921-12-161.

Bleecker ER, Siler T, Owen R, Kramer B. Bronchodilator efficacy and safety of indacaterol 150 µg once daily in patients with COPD: an analysis of pooled data. Int J Chron Obstruct Pulmon Dis. 2011;6:431-8. doi: 10.2147/COPD.S21073. Epub 2011 Aug 18.

Feldman G, Siler T, Prasad N, Jack D, Piggott S, Owen R, Higgins M, Kramer B; INLIGHT 1 study group. Efficacy and safety of indacaterol 150 microg once-daily in COPD: a double-blind, randomised, 12-week study. BMC Pulm Med. 2010 Mar 8;10:11. doi: 10.1186/1471-2466-10-11.

Responsible Party:	External Affairs, Novartis
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Other Study ID Numbers:	**CQAB149B2346** EUDRACT Number: 2008-000301-11
Study First Received:	February 15, 2008
Results First Received:	July 22, 2011
Last Updated:	July 22, 2011
Health Authority:	Australia: Department of Health and Ageing Therapeutic Goods Administration Belgium: Federal Agency for Medicinal Products and Health Products Denmark: Danish Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices India: Institutional Review Board Italy: National Bioethics Committee Lithuania: State Medicine Control Agency - Ministry of Health Netherlands: Medicines Evaluation Board (MEB) Singapore: Health Sciences Authority Sweden: Medical Products Agency Taiwan: Department of Health

United Kingdom: Medicines and Healthcare Products Regulatory Agency
United States: Food and Drug Administration