

# Study of the impact of indacaterol on the individual lives and health status of patients with chronic obstructive pulmonary disease (COPD)

<b>Submission date</b> 11/04/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/06/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Clinical studies provide useful information regarding both the safety and effectiveness of medicines, but clinical trial settings are not always as close to a real-world setting as they could be, often due to the excluding of patients taking specific medications or with other specific conditions, and the patients are also often intensively monitored throughout the study. Indacaterol is a drug used for the treatment of chronic obstructive pulmonary disease (COPD). It is taken once a day to open up the airways that will have become narrowed as part of the disease process of COPD. The aim of this study is to measure the impact of indacaterol on individual patients in a real-world setting, where the patients have been prescribed indacaterol as their standard therapy following a clinical assessment for their COPD.

### Who can participate?

The study is open to patients in selected GP practices in the UK that have chosen to participate. Patients must be aged over 18 and have been prescribed indacaterol for COPD.

### What does the study involve?

This study uses data from routine clinical examinations. In addition to standard measurements, patients will also be requested to complete two straightforward questionnaires at specified timepoints during the study and will also be requested to rate their overall opinion of the effectiveness of indacaterol at the end of the study. Patients in the study will be monitored for a total of 6 months, with a visit between 6 and 8 weeks after the start of the study.

### What are the possible benefits and risks of participating?

There may be a potential benefit for participating patients in terms of improved monitoring of their COPD, though this study has been designed to be close to the standard monitoring of COPD patients starting a new medication. The only potential impact for patients is the short amount of time required to complete the two short questionnaires.

Where is the study run from?  
Novartis Pharmaceuticals UK Ltd.

When is the study starting and how long is it expected to run for?  
From April 2012 to August 2013.

Who is funding the study?  
Novartis Pharmaceuticals UK Ltd.

Who is the main contact?  
Dr Amr Radwan

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Amr Radwan

**Contact details**  
Novartis Pharmaceuticals UK Ltd  
200 Frimley Business park  
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United Kingdom  
GU16 7SR

## Additional identifiers

**Protocol serial number**  
CQAB149BGB01

## Study information

**Scientific Title**  
INdacaterol effect on Health status in COPD: A real Life patient Experience prospective observational study (INHALE)

**Acronym**  
INHALE

**Study objectives**  
Whilst there have been clinical trials of indacaterol showing the improvement of objective measures of COPD such as Forced expiratory volume in one second (FEV1) and dyspnoea score, there is to date no information on its impact on individual patient lives in the real world. Novartis are keen to undertake a prospective observational study of the impact of indacaterol on individual patient lives in the real world by looking at patient experience in the nonRCT population.

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

This observational study will be submitted for ethical review via the National Research Ethics Service (NRES) and appropriate PCT (or equivalent) and practice research governance approval will be obtained before the study commences in each location. Patient consent will be sought for participation in the study.

### **Study design**

Prospective observational multicentre research study in GP practices clustered within up to 10 UK primary care trusts (PCTs)

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Chronic obstructive pulmonary disease (COPD)

### **Interventions**

Patients in the study will have been prescribed indacaterol as part of routine clinical practice. Patients will be asked to complete the COPD Assessment Test (CAT) at baseline, 6-8 weeks and 6 months after initiation, a life impact questionnaire at 6-8 weeks after initiation and a Global Evaluation of Treatment Effectiveness (GETE) questionnaire at 6 months after initiation.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Absolute CAT scores and mean standard deviation (SD) change from baseline in CAT score at 68 weeks after initiation of indacaterol

### **Key secondary outcome(s)**

1. Mean (SD) change from baseline in CAT score at 6 months after initiation of indacaterol
2. Qualitative description of the impact of indacaterol on the patients' life at 68 weeks after initiation of indacaterol
3. Distribution and summary statistics of physician GETE at 68 weeks and 6 months after initiation of indacaterol
4. Distribution and summary statistics of patient GETE at 6 months after initiation of indacaterol
5. Distribution and summary statistics of FEV1 throughout the observation period
6. Distribution and summary statistics of MRC dyspnoea scores throughout the observation period
7. Description of study sample at baseline

### **Completion date**

01/10/2013

# Eligibility

## Key inclusion criteria

1. Patients with active diagnosis of COPD, confirmed by spirometry, documented in medical notes
2. Patients who are newly prescribed indacaterol as part of routine clinical practice

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

1. Patients who have previously received maintenance therapy for COPD symptoms e.g. Long acting beta agonists (LABAs), long acting antimuscarinics (LAMAs), LABA + inhaled corticosteroid (ICS)
2. Patients unable or unwilling to consent to participation in the study
3. Patients unable or unwilling to complete the study questionnaires
4. Patients who have participated in any interventional clinical trial for indacaterol
5. Patients who have previously been prescribed indacaterol

## Date of first enrolment

01/05/2012

## Date of final enrolment

01/10/2013

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

Novartis Pharmaceuticals UK Ltd

Frimley

United Kingdom

GU16 7SR

# Sponsor information

## Organisation

Novartis Pharmaceuticals UK Ltd (UK)

## ROR

<https://ror.org/039s6n838>

# Funder(s)

## Funder type

Industry

## Funder Name

Novartis Pharmaceuticals (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration