

# The effect of fluticasone and formoterol in combination administered through Dry Powder Inhaler (DPI) versus budesonide and formoterol in combination (Symbicort Turbuhaler) in the maintenance treatment of asthma in adults.

<b>Submission date</b> 05/01/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/03/2014	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English Summary

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Heloisio Rodrigues

### Contact details

Rua Josef Kryss, 250  
São Paulo  
Brazil  
01140-050

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Prospective, open, multicentre study on the effect of fluticasone and formoterol in combination administered through Dry Powder Inhaler (DPI) compared to budesonide and formoterol in combination (Symbicort Turbuhaler) in the maintenance treatment of asthma in adults.

### Acronym

DUONARE

### Study hypothesis

The fixed combination of a corticosteroid with a long action bronchodilator has been used in the control of moderate to severe asthma. Isolated fluticasone and isolated formoterol are approved for asthma control treatment. The aim of this study is to prove that the combination of fluticasone and formoterol is safe and effective.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Local ethics approval was issued on the 4th of January 2010 by Ethic Committee of São Paulo Federal University/São Paulo Hospital (ref: CEP 1770/09)

### Study design

Randomised open label active controlled parallel group safety and efficacy study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### Condition

Asthma

### Interventions

Subjects will be randomised to receive either fluticasone 250mcg + formoterol 12mcg (Duonare®) or budesonide 400mcg plus formoterol 12 mcg (Symbicort Turbuhaler®) twice daily (BID).

Subjects will record their compliance with the twice daily inhaler dosing, diary questions and

peak expiratory rates will also be recorded twice daily  
Six clinic visits will be foreseen. In all visits, subjects will be submitted to a pulmonary function test.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Fluticasone plus Formoterol (Duonare®), Budesonide plus Formoterol (Symbicort Turbuhaler®)

### **Primary outcome measure**

Evaluate the effect of the combined fluticasone and formoterol DPI BID for 12 weeks compared to the combined budesonide and formoterol Turbuhaler BID for 12 week using morning peak expiratory flow rate (PEFR)

### **Secondary outcome measures**

1. FEV1
2. Evening peak expiratory flow rate (PEFR)
3. Clinical endpoints
  - 3.1. frequency of asthma exacerbations & symptoms
  - 3.2. rescue medication and others patient data captured in diary)

### **Overall study start date**

01/04/2010

### **Overall study end date**

01/06/2011

## **Eligibility**

### **Participant inclusion criteria**

1. Male or female from 18 to 65 years old with known history of asthma according to Global Initiative for Asthma (GINA) update 2008 criteria for at least three months.
2. Patients with partially controlled or non-controlled asthma using therapeutic doses of inhaled corticosteroid combined with long-acting bronchodilator (daily doses equal or more than 400 mcg of budesonide or similar drugs) for at least four weeks
3. Forced Expiratory Volume in 1 second (FEV1) > 60 % of predicted normal value
4. Willing and able to keep diary and attend all visits
5. Written informed consent obtained

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

234 patients

**Participant exclusion criteria**

1. Pregnant or nursing women
2. Females of childbearing potential without an effective method of birth control
3. Use of systemic corticosteroid within 30 days before randomization
4. Three or more treatments with oral corticosteroid or history of asthma hospitalization in the previous six months
5. Use of the following drugs within two weeks before randomization:
  - 5.1. methylxanthines
  - 5.2. monoaminooxidases
  - 5.3. beta-blockers
  - 5.4. acetylcysteine
  - 5.5. carbocysteine
  - 5.6. tricyclic antidepressants
  - 5.7. sodium channel blockers
  - 5.8. leukotrienes
  - 5.9. anticholinergics
  - 5.10. phenothiazines
  - 5.11. immunotherapy
  - 5.12. levodopa
  - 5.13. ritonavir
  - 5.14. oral ketoconazole
6. Current evidence of history of hypersensitivity to the study drug
7. Evidence of non-adherence to the treatment during run-in phase
8. A smoking history equivalent to "10 pack years" (i.e., at least 1 pack of 20 cigarettes/day for 10 years or 10 packs/day for 1 year, etc)
9. Clinically significant laboratory test results during the screening phase
10. Morning serum level of cortisol < 5 mcg/dL
11. Inability to perform the lung function test
12. Current evidence of other pulmonary disease
13. Patients with asthma exacerbation during the run-in period
14. Evidence of clinically significant oral candidiasis

**Recruitment start date**

01/04/2010

**Recruitment end date**

01/06/2011

**Locations**

**Countries of recruitment**

Brazil

**Study participating centre**  
Rua Josef Kryss, 250  
São Paulo  
Brazil  
01140-050

## **Sponsor information**

### **Organisation**

Libbs Pharmaceutical Ltd (Brazil)

### **Sponsor details**

Rua Josef Kryss, 250  
São Paulo  
Brazil  
01140-050

### **Sponsor type**

Industry

### **Website**

<http://www.libbs.com.br/Home.aspx>

### **ROR**

<https://ror.org/055kp8612>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Libbs Pharmaceutical Ltd (Brazil)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2013		Yes	No