# 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.

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

**Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### 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 objectives

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

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

Asthma

#### Interventions

Subjects will be randomised to receive either futicasone 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 are 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

### Completion date

01/06/2011

# **Eligibility**

#### Key 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

#### Sex

Both

# Target number of participants

234 patients

## Key exclusion criteria

- 1. Pregnant or nursing womem
- 2. Females of childbearing potential withoud 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. meltixantines
- 5.2. monoaminoxidases
- 5.3. beta-blockers
- 5.4. acetilscisteine
- 5.5. carbocisteine
- 5.6. triciclic antidepressive
- 5.7. sodium channel blockers
- 5.8. leukotriene
- 5.9. anticolinergic
- 5.10. phenotiazidics
- 5.11. immunotherapy
- 5.12. levodopa
- 5.13. ritonavir
- 5.14. oral ketoconozal
- 6. Current evidence of history of hypersensitivity to the study drug
- 7. Evidence of non-adhesion 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

#### Date of first enrolment

01/04/2010

#### Date of final enrolment

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?
Results article	results	01/09/2013		Yes	No