

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 05/01/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 20/01/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/03/2014	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LB0807

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)

Primary study design

Interventional

Study design

Randomised open label active controlled parallel group safety and efficacy study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnant or nursing womem
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. melitixantines
 - 5.2. monoaminoxidases

- 5.3. beta-blockers
- 5.4. acetilscisteine
- 5.5. carbocisteine
- 5.6. tricyclic antidepressive
- 5.7. sodium channel blockers
- 5.8. leukotriene
- 5.9. anticholinergic
- 5.10. phenothiazides
- 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

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)

ROR

https://ror.org/055kp8612

Funder(s)

Funder type

Industry

Funder Name

Libbs Pharmaceutical Ltd (Brazil)

Results and Publications

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