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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/01/2010	**Overall study status** Completed	
Last Edited 26/03/2014	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

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

18 Years

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