FAIR-study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23638

Source
NTR

Brief title
CCD-1007-PR-0045

Health condition

Chronic Obstructive Pulmonary Disease

Sponsors and support

Primary sponsor: CROMSOURCE – Quality System Certified ISO 9001
Lange Dreef 11H, NL-4131 NJ Vianen, The Netherlands
Source(s) of monetary or material Support: CHIESI Farmaceutici S.p.A. – Via Palermo 26/A
43122 Parma – Italy

Intervention

Outcome measures

Primary outcome

To demonstrate the higher efficacy of small particles Foster® 100/6 (two puffs b.i.d.) versus large particles Symbicort® 200/6 (two inhalations b.i.d.), in terms of residual volume reduction in patients with Chronic Obstructive Pulmonary Disease.

This will be proven by measuring the change from baseline to end of treatment in post-dose residual volume.

Secondary outcome

To evaluate the efficacy of the test treatments in terms of reduction of symptoms, improvements in health status (assessed by specific questionnaires) and in parameters related to small airway function in patients with Chronic Obstructive Pulmonary Disease, and to assess the safety of study treatments.

These will be confirmed by:

1. Changes from baseline in FEV1, FVC, FEV1/FVC, IVC/FVC, RV, TLC, RV/TLC, FRC, FRC/TLC, RV/VC, Raw, eff and sGaw, eff;

2. Changes from baseline in airways resistance (R5, R20, R5-20) and reactance at 5 Hertz (X5) (in a subset of at least 50% of patients from pre-selected sites);

3. Changes from baseline in COPD symptom scores (for each single score and the total score);

4. Change from baseline in percentage of COPD symptom-free days;

5. Change from baseline in rescue salbutamol or ipratropium bromide consumption (puffs per day);

6. Change from baseline in percentage of rescue salbutamol or ipratropium bromide-free days;

7. Transition Dyspnoea Index (TDI) score at day 84 (V4);

8. Clinical COPD Questionnaire (CCQ);

9. Physical activity (by means of pedometer);

10. Nasal brushing (mRNA expression);

11. Number of patients with COPD exacerbations.

Study description

Background summary

A 12-week, multicentre, randomised, double-blind, double-dummy, 2-arm parallel group

study comparing the efficacy and safety of Foster® 100/6 (beclomethasone dipropionate 100 µg plus formoterol 6 µg/actuation), 2 puffs b.i.d., versus Symbicort® 200/6 (budesonide 200 µg plus formoterol fumarate 6 µg/actuation), 2 inhalations b.i.d., on parameters of small airway function in patients with Chronic Obstructive Pulmonary Disease.

Primary objectives:

To demonstrate the higher efficacy of small particles Foster® 100/6 (two puffs b.i.d.) versus large particles Symbicort® 200/6 (two inhalations b.i.d.), in terms of residual volume reduction in patients with Chronic Obstructive Pulmonary Disease.

Secondary objectives:

To evaluate the efficacy of the test treatments in terms of reduction of symptoms, improvements in health status (assessed by specific questionnaires) and in parameters related to small airway function in patients with Chronic Obstructive Pulmonary Disease, and to assess the safety of study treatments.

Study objective

To demonstrate the higher efficacy of small particles Foster® 100/6 (two puffs b.i.d.) versus large particles Symbicort® 200/6 (two inhalations b.i.d.), in terms of residual volume reduction in patients with Chronic Obstructive Pulmonary Disease.

Study design

Visit 0 (pre-screening visit/Week -5):

A pre-screening visit will be carried out in order to fully explain the study to eligible COPD patients.
The following procedures will take place:

1. The written informed consent will be obtained from the patients or the legal representatives (if applicable);

2. The patient will be identified by a number of four digits. The first two digits will identify the centre and the last two digits will identify the patient’s number (patient’s ID) sequentially assigned to each patient of each centre according to a chronological order (i.e. for the first patient selected they will be 01, 02 for the second patient and so on);

3. Instruction will be given to the patients for the next visit (V1);

4. The investigator will have to verify the absence of COPD exacerbations in the previous 2 months as required in the inclusion criteria;

5. Any adverse event (AE) occurring since the signature of the informed consent will be monitored and recorded in the e-CRF.

An appointment for the screening visit (V1) will be taken within 7 days ± 3 in the morning. Patients will be instructed:

1. To fasten overnight for the next visit in order to perform blood sampling;

2. Not to take rescue salbutamol pMDI or other SABAs in the 6 hours preceding the next visit, unless absolutely necessary;

3. Not to take LABAs or ICS/LABA combinations in the 12 hours preceding the next visit;

4. Not to take long-acting anticholinergics medication 72 hours preceding the next visit and short-acting anticholinergics medication 12 hours preceding the next visit;

5. Not to take combination of a SABA and a short-acting anticholinergic medication 12 hours preceding the next visit.

Visit 1 [screening visit/Start of the run-in period/Week -4 (±3 days)]:

A screening visit will be carried out between 8:00 and 11:00 a.m. in order to enrol eligible consenting COPD patients in the study.
The following procedures will take place:

1. If rescue salbutamol pMDI or other SABAs have been inhaled in the previous 6 hours, visit needs to be re-scheduled (2 days' window). If salbutamol or other SABAs' intake occurs again in the 6 hours prior to the postponed visit, the patient will be withdrawn from the study;

2. If LABAs and/or ICSs have been inhaled in the previous 12 hours, visit needs to be re-scheduled (2 days' window). If intake occurs again before the postponed visit, the patient will be withdrawn from the study;

3. If short-acting anticholinergic medications have been inhaled in the previous 12 hours, visit needs to be re-scheduled (2 days' window). If intake occurs again before to the postponed visit, the patient will be withdrawn from the study;

4. If long-acting anticholinergic medications have been inhaled in the previous 72 hours, visit needs to be re-scheduled (3 days' window). If intake occurs again before to the postponed visit, the patient will be withdrawn from the study;

5. A complete medical history will be recorded, including adverse events (both allergies and adverse drug reactions) to inhaled medications, if any. All medications being taken by the patient will be recorded in the e-CRF. Intake of non-permitted medication constitutes a non-eligibility criterion for enrolment in the study;

6. All inclusion/exclusion criteria will be assessed;

7. A full physical examination will be performed;

8. Vital signs [heart rate (HR), systolic (SBP) and diastolic (DBP) blood pressure)] will be measured, after 10 minutes of rest, in sitting position;

9. The Baseline Dyspnoea Index (BDI) score will be completed at the clinic visit by the patient to assess dyspnoea (see Appendix VIII) under medical supervision. Only patients with a BDI focal scores 10 will be eligible;

10. The Clinical COPD Questionnaire (CCQ) will be completed at the clinic visit by the patient to assess health status under medical supervision (see Appendix IX). The patient will be trained in the proper completion of the CCQ and will be asked to record his/her experiences during the last seven days;

11. 12-lead ECG evaluation by local laboratory;

12. A nasal brushing will be performed to assess airway gene expression patterns (see procedures in section 7.2);

13. Spirometry will be performed to assess pre-bronchodilator FEV1 and FVC (see procedures in section 7.2);

14. Body plethysmography will be performed to assess pre-bronchodilator FRC (see procedures in section 7.2);

15. IOS will be performed to assess pre-bronchodilator R5, R20 and X5 (in a subgroup of at least 50% of patients from pre-selected sites) (see procedures in section 7.2);

16. Spirometry and IOS will be repeated 30 minutes after the inhalation of 4 puffs (4 100 µg) of salbutamol pMDI. Only patients with a pre-bronchodilator FRC > 120% of the predicted normal value, a post-bronchodilator FEV1 < 65% of the predicted normal value, an FEV1/FVC < 0.7 and an increase in FEV1 < 15% and < 200 mL from baseline following administration of salbutamol will be eligible;

17. Blood sample will be collected between 8:00 and 9:00 a.m. after overnight fasting in order to perform the following determinations (see section 7.2):

A. Routine haematology/blood chemistry;

B. Serum -HCG test (if appropriate). In case of non interpretable data, another determination

must be performed as soon as possible.

18. AEs occurred since the signature of the informed consent will be recorded. In case of any clinically significant abnormality revealed during the physical examination or screening procedures, it will be recorded in the patient's medical history, unless its start date is after the informed consent signature date. In this case it will be recorded as an adverse event;

19. Patient will be trained in the proper use of the pMDI and the DPI (see section 6.4.4) with training kits;

20. The following drugs will be dispensed:

A. Symbicort® Turbohaler® 200/6 µg/unit dose (1 inhalation b.i.d.) for the run-in period;

B. Ventolin Evohaler or Atrovent® Inhaler CFC-Free 20 µg for as needed use during the run-in and the study period. The investigator, according to his/her clinical judgment and to the patient's medical history, will decide about dispensing Atrovent® Inhaler CFC-Free 20 or Ventolin Evohaler.

21. The diary card will be handed out to the patient for daily recording of run-in treatment and rescue medication (number of puffs) intake. The patients will also have to record each morning COPD symptom scores (including night-time awakenings);

22. An appointment for visit 2 will be taken in 28 (±3) day's time in the morning (between 8:00 and 11:00 a.m.);

23. Patients will be instructed:

A. Not to take salbutamol or ipratropium bromide in the 6 hours preceding the next visit, unless absolutely necessary;

B. Not to take the run-in medication later than 12 hours before coming to the clinic visit (the study drug will be administered at visit 2 under the supervision of the investigator);

C. To bring back the study medications at the next visit.

24. A card with the investigator's contact details will be handed out to the patient.

Visit 2 [End of run-in period/Randomisation to treatments/Start of treatment period/Week 0 (±3 days)].

Visit 2 procedures will start between 8:00 and 11:00 a.m.

1. If rescue salbutamol has been inhaled in the previous 6 hours, visit needs to be re-scheduled (2 days' window). If salbutamol intake occurs again in the 6 hours prior to the

postponed visit, the patient will be withdrawn from the study;

2. If rescue ipratropium bromide has been inhaled in the previous 6 hours, visit needs to be re-scheduled (2 days' window). If ipratropium bromide intake occurs again in the 6 hours prior to the postponed visit, the patient will be withdrawn from the study;

3. If run-in medication have been inhaled in the previous 12 hours, visit needs to be re-scheduled (2 days' window). If Symbicort® Turbohaler® 200/6 intake occurs again before the postponed visit, the patient will be withdrawn from the study;

4. A full physical examination will be performed;

5. Changes of concomitant medications being taken by the patient will be recorded. In the case of intake of any non-permitted concomitant medication, the patient will be withdrawn from the study;

6. The occurrence of adverse events (if any) will be checked and recorded;

7. The occurrence of COPD exacerbations (if any) will be evaluated and annotated in the e-CRF (see section 7.2). In case of COPD exacerbations during the run-in period, the patient will be withdrawn from the study;

8. Diary card will be checked for any discrepancy;

9. Vital signs [heart rate (HR), systolic (SBP) and diastolic (DBP) blood pressure] will be evaluated at pre-dose;

10. The Baseline Dyspnoea Index (BDI) score will be completed at the clinic visit by the patient to assess dyspnoea (see Appendix VIII) under medical supervision. Only patients with a BDI focal scores 10 can be randomised;

11. The Clinical COPD Questionnaire (CCQ) will be completed at the clinic visit by the patient to assess health status under medical supervision (see Appendix IX). The patient will be asked to record his/her experiences during the last seven days;

12. A nasal brushing will be performed at pre-dose to assess airway gene expression patterns (see procedures in section 7.2);

13. Body plethysmography and IOS (the latter in a subgroup of at least 50% of patients from pre-selected sites) prior drug intake (see section 7.2);

14. Patient will be trained in the proper use of the pMDI and the DPI (see section 6.4.4) with training kits;

15. A randomisation number will be assigned to each eligible patient (see section 6.5);

16. After 10 minutes rest from pletysmographic measurements, the test treatments

corresponding to the randomisation number of the patient will be administered by using pMDI and DPI inhalers. The directions for use of the treatments will be reminded to the patient, with the help of diagrams from the package insert demonstrating the correct inhalation technique (Appendix III). The administration will be supervised by the investigator, who will ensure the correct procedure. In each session, the administration with the pMDI will precede that with the DPI inhalers; a 30-second time interval between the inhalations is recommended. For the subsequent administrations, patients will be instructed to take the study drug in the morning and in the evening to possible extent at the same time. The patients will be instructed to keep the study drugs at room temperature < 25 ˚C but not in the refrigerator;

17. Body plethysmography and IOS (the latter in a subgroup of at least 50% of patients from pre-selected sites) (see section 7.2) will be repeated 120 and 180 minutes after the inhalation of test treatments;

18. Diary card will be handed out to the patient for daily recording of study drug intake. The patient will be reminded on the other information to be recorded in the diary;

19. The study medications for the following 4 weeks of treatment will be handed out to the patient, and the tear-off sticker from the medication box will be applied in a specific Drug Dispensing Form;

20. A portable electronic pedometer will be handed out to the patient for recording of steps measured each day of the two weeks before each clinic visit;

21. An appointment for visit 3 will be taken in 4 weeks' time (at approximately the same time as the other visits) and the patients will be instructed:

A. Not to take salbutamol or ipratropium bromide in the 6 hours preceding the next visit, unless absolutely necessary;

B. Not to take the study drug in the morning (12 hours before coming to the clinic visit) of the next visit (study drug will be administered at the clinic visit);

C. To bring back the study medications at the next visit.

Visit 3 [Week 4 (-3 to +3 days)]:

Visit 3 procedures will start between 8:00 and 11:00 a.m.

1. If rescue salbutamol has been inhaled in the previous 6 hours, visit needs to be re-scheduled (2 days' window). If salbutamol intake occurs again in the 6 hours prior to the postponed visit, the patient will be withdrawn from the study;

2. If rescue ipratropium bromide has been inhaled in the previous 6 hours, visit needs to be

re-scheduled (2 days' window). If ipratropium bromide intake occurs again in the 6 hours prior to the postponed visit, the patient will be withdrawn from the study;

3. If study medications have been inhaled in the previous 12 hours, visit needs to be re-scheduled (2 days' window). If intake occurs again before the postponed visit, the patient will be withdrawn from the study;

4. A full physical examination will be performed;

5. Changes of concomitant medications being taken by the patient will be recorded. In the case of intake of any non-permitted concomitant medication, the patient will be withdrawn from the study;

6. The occurrence of adverse events (if any) will be checked and recorded;

7. Consumption of medical resources: unplanned medical visits or emergency room visits, laboratory tests, instrumental diagnostics, hospital admissions and working days lost (by the patient and the caregiver), will be collected since visit 2;

7. The occurrence of COPD exacerbations (if any) will be evaluated and annotated in the e-CRF (see section 7.2). In case of COPD exacerbations during the previous 4 weeks of treatment, the patient will be withdrawn from the study;

8. Diary card will be checked for any discrepancy;

9. Vital signs [heart rate (HR), systolic (SBP) and diastolic (DBP) blood pressure] will be evaluated at pre-dose;

10. Body plethysmography and IOS (the latter in a subgroup of at least 50% of patients from pre-selected sites) prior drug intake (see section 7.2);

11. After 10 minutes rest from pletysmographic measurements, the test treatments corresponding to the randomisation number of the patient will be administered by using pMDI and DPI inhalers. The directions for use of the treatments will be reminded to the patient, with the help of diagrams from the package insert demonstrating the correct inhalation technique (Appendix III). The administration will be supervised by the investigator, who will ensure the correct procedure. In each session, the administration with the pMDI will precede that with the DPI inhalers; a 30-second time interval between the inhalations is recommended. For the subsequent administrations, patients will be instructed to take the study drug in the morning and in the evening to possible extent at the same time. The patients will be instructed to keep the study drugs at room temperature < 25 ˚C but not in the refrigerator;

12. Body plethysmography and IOS (the latter in a subgroup of at least 50% of patients from pre-selected sites) (see section 7.2) will be repeated 120 and 180 minutes after the inhalation of test treatments;

13. Diary card will be handed out to the patient for daily recording of study drug intake. The patient will be reminded on the other information to be recorded in the diary;

14. The study medications for the following 8 weeks of treatment will be handed out to the patient, and the tear-off sticker from the medication box will be applied in a specific Drug Dispensing Form;

15. An appointment for visit 4 will be taken in 8 weeks' time (at approximately the same time as the other visits) and the patients will be instructed:

A. Not to take salbutamol or ipratropium bromide in the 6 hours preceding the next visit, unless absolutely necessary;

B. Not to take the study drug in the morning (12 hours before coming to the clinic visit) of the next visit (study drug will be administered at the clinic visit);

C. To bring back the study medications at the next visit.

Phone contact [Week 8 (-2 to +2 days)]:

8 weeks after the first study medication intake all patients will be contacted and the status on any unresolved AEs at visit 3 and on any AEs/SAEs that have occurred after visit 3 will be checked and recorded. Also new concomitant medications received since the previous visit and any consumption of medical resources will have to be recorded in the e-CRF.

Visit 4 [Week 12 (-3 to +3 days)]:

Visit 4 procedures will start between 8:00 and 11:00 a.m.

1. If rescue salbutamol has been inhaled in the previous 6 hours, visit needs to be re-scheduled (2 days' window). If salbutamol intake occurs again in the 6 hours prior to the postponed visit, the patient will be withdrawn from the study;

2. If rescue ipratropium bromide has been inhaled in the previous 6 hours, visit needs to be re-scheduled (2 days' window). If ipratropium bromide intake occurs again in the 6 hours prior to the postponed visit, the patient will be withdrawn from the study;

3. If study medications have been inhaled in the previous 12 hours, visit needs to be re-scheduled (2 days' window). If intake occurs again before the postponed visit, the patient will be withdrawn from the study;

4. A full physical examination will be performed;

5. Changes of concomitant medications being taken by the patient will be recorded. In the case of intake of any non-permitted concomitant medication, the patient will be withdrawn from the study;

6. The occurrence of adverse events (if any) will be checked and recorded;

7. The occurrence of COPD exacerbations (if any) will be evaluated and annotated in the e-CRF (see section 7.2). In case of COPD exacerbations during the previous 8 weeks, the patient will be withdrawn from the study;

8. Diary card will be collected and checked for any discrepancy;

9. Vital signs [heart rate (HR), systolic (SBP) and diastolic (DBP) blood pressure] will be evaluated at pre-dose;

10. The Transition Dyspnoea Index (TDI) score will be completed at the clinic visit by the patient to assess dyspnoea (see Appendix VIII) under medical supervision;

11. The Clinical COPD Questionnaire (CCQ) will be completed at the clinic visit by the patient to assess health status under medical supervision (see Appendix IX). The patient will be asked to record his/her experiences during the last seven days;

12. 12-lead ECG evaluation by local laboratory;

13. A nasal brushing will be performed at pre-dose to assess airway gene expression patterns (see procedures in section 7.2);

14. Body plethysmography and IOS (the latter in a subgroup of at least 50% of patients from pre-selected sites) prior drug intake (see section 7.2);

15. Blood sample will be collected between 8:00 and 9:00 a.m. after overnight fasting in order to perform the following determinations (see section 7.2):

A. Routine haematology/blood chemistry;

B. Serum □-HCG test (if appropriate). In case of non interpretable data, another determination must be performed as soon as possible.

16. After 10 minutes rest from pletysmographic measurements, the test treatments corresponding to the randomisation number of the patient will be administered by using pMDI and DPI inhalers. The directions for use of the treatments will be reminded to the patient, with the help of diagrams from the package insert demonstrating the correct inhalation technique (Appendix III). The administration will be supervised by the investigator, who will ensure the correct procedure. In each session, the administration with the pMDI will precede that with the DPI inhalers; a 30-second time interval between the inhalations is recommended;

17. Body plethysmography and IOS (the latter in a subgroup of at least 50% of patients from pre-selected sites) (see section 7.2) will be repeated 120 and 180 minutes after the inhalation of test treatments;

18. The portable electronic pedometer will be collected and checked for any discrepancy.

Follow-up phone contact:

7-10 days after the last study medication intake all patients will be contacted and the status on any unresolved AEs at the last visit will be checked and recorded. Also new concomitant medications received since the previous visit will have to be recorded in the e-CRF. SAEs that are still ongoing at the time of the follow-up contact will be monitored until clinical recovery is complete, until progression has been stabilized or the patient is lost to follow-up.

Intervention

During the run-in period of 4weeks between screening and randomisation, subjects will be asked to use Symbicort® Turbohaler® 200/6 µg/unit dose 1 inhalation b.i.d.
(daily dose of BUD 400 µg plus FF 12 µg). After randomisation, subjects will be enrolled in either:

1. Treatment A: Foster® (beclomethasone dipropionate 100 µg plus formoterol 6 µg/unit dose), 2 inhalations b.i.d. (daily dose of BDP “extrafine” 400 µg plus FF 24 µg);

2. Treatment B: Symbicort® Turbohaler® (budesonide 200 µg plus formoterol fumarate 6 µg/actuation), 2 inhalations b.i.d. (daily dose of BUD 800 µg plus FF 24 µg).

After which the treatment phase of 12 weeks will start. After 12 weeks the study stops and a short followup phase of 7-10 days is applicable.

Contacts

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Scientific
UMCG

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Eligibility criteria

Inclusion criteria

1. Male or female patients aged ≥ 40 years, who have signed an Informed Consent form prior to initiation of any study-related procedure or when applicable written informed consent obtained by legal representative;

2. Outpatients with a clinical diagnosis of moderate to severe COPD and including:

A. Smoking history of at least 10 pack years defined as [(number of cigarettes smoked per day) x (number of years of smoking)] / 20, both current and ex-smokers are eligible;

B. Regular use of bronchodilators (e.g. β2-agonist, anticholinergics) in the 2 months before visit 1;

C. Post-bronchodilator FEV1 < 65% of the predicted normal value at visit 1;

D. Post-bronchodilator FEV1/FVC < 0.7 at visit 1;

E. An increase in FEV1 < 15% and < 200 mL from baseline following administration of 400 µg of salbutamol at visit 1;

F. Plethysmographic Functional Residual Capacity (FRC) > 120% of the predicted normal value (at visit 1 and visit 2);

G. A Baseline Dyspnoea Index (BDI) focal score smaller then or equal to 10 (at visit 1 and at visit 2).

3. A cooperative attitude and ability to be trained to the proper use of pMDI and DPI (Turbohaler®, inspiratory flow-driven, multidose powder inhaler) inhalers.

Exclusion criteria

1. Diagnosis of asthma or other clinically or functionally relevant respiratory disorders (other

than COPD) which may interfere with data interpretation according to the investigator's opinion;

2. Pregnant or lactating women. Females of childbearing potential without an efficient contraception UNLESS they meet the following definition of post-menopausal: 12 months of natural (spontaneous) amenorrhea or 6 months of spontaneous amenorrhea with serum FSH levels > 40 mIU/mL or are using one or more of the following acceptable methods of contraception:

A. Surgical sterilization (e.g. bilateral tubal ligation, hysterectomy);

B. Hormonal contraception (implantable, patch, oral, injectable);

C. Barrier methods of contraception: condom or occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/cream/suppository;

D. Continuous abstinence (e.g. nuns);

E. Periodic abstinence (e.g. calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception. Reliable contraception should be maintained throughout the study and for 30 days after study drug discontinuation.

3. Clinically unstable concurrent disease: e.g. hyperthyroidism, diabetes mellitus or other endocrine disease; significant hepatic impairment; significant renal impairment; cardiovascular disease (e.g. coronary artery disease, hypertension, heart failure); gastrointestinal disease (e.g. active peptic ulcer); neurological disease; haematological disease; autoimmune disorders, or other which may impact the evaluation of the results of the study according to investigator's judgement;

4. Patient with narrow-angle glaucoma;

5. Clinically significant laboratory and ECG abnormalities indicating a significant or unstable concomitant disease which may impact the evaluation of the results of the study and the safety of the patient according to investigator's judgement;

6. Patients with COPD exacerbation and/or symptomatic infection of the airways requiring antibiotic therapy (at least 5 days) in the 2 months prior to screening and during the study period. COPD exacerbation will be defined according to the following: "A sustained worsening of the patient's condition (dyspnoea, cough and/or sputum production/purulence), from the stable state and beyond normal day-to-day variations, that is acute in onset and necessitates a change in regular medication in a patient with underlying COPD that includes prescriptions of systemic corticosteroids (at least 3 days) and/or antibiotics (at least 5 days), or need for a visit to an emergency department or hospitalization";

7. Patients requiring long term (> 12 hours daily) oxygen therapy for chronic hypoxemia;

8. Patients treated with depot corticosteroids in the 2 months preceding the visit 1 and during

the run-in period;

9. Patients with known allergy, sensitivity or intolerance to sympathomimetic drugs or inhaled corticosteroids or to any of the excipients contained in the study drugs;

10. Patients who have evidence of alcohol or drug abuse, not compliant with the study protocol or not compliant with the study treatments according to investigator's judgement;

11. Major surgery in the previous 3 months and during the trial which may affect patient's compliance in study procedures (e.g. plethysmography);

12. Participation in another clinical trial with an investigational drug in the 2 months preceding visit 1;

13. Patients requiring chronic mechanical ventilation for COPD.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-09-2011
Enrollment:	144
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2805
NTR-old	NTR2946
Other	METC UMCG : 2011-130
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A