ongoing trials - trial from other registries

Long Term Administration of Inhaled Dry Powder Mannitol In Cystic Fibrosis â€“ A Safety and Efficacy Study - Completed

Code: EUCTR2006-004078-28-GB **Year:** 2012 **Date:** **Author:** Pharmaxis

Study design (if review, criteria of inclusion for studies)

Completed. No study results posted - Study type: Interventional clinical trial of medicinal product. Study design: Controlled: yes Randomised: yes Open: yes Double blind: yes Parallel group: yes Placebo: yes "Placebo" = Sub-therapeutic control

Participants

Inclusion criteria: Subjects may be included in the study if all of the following criteria are met. The subject must: 1. Have given written informed consent to participate in this study in accordance with local regulations 2. Have a confirmed diagnosis of cystic fibrosis 3. Be aged >= 6 years 4. Have FEV1 >=30 % and <90% predicted 5. Be able to perform all the techniques necessary to measure lung function Are the trial subjects under 18? yes Adults (18-64 years) yes Elderly (>=65 years) yes Exclusion criteria: Subjects are excluded from participating in this study if one or more of the following criteria are met. The subject must NOT: 1. Be investigators, site personnel directly affiliated with this study, and their immediate families. Immediate family is defined as a spouse, parent, child or sibling, whether biologically or legally adopted. 2. Be considered "terminally ill"Â• or listed for lung transplantation 3. Have had a lung transplant 4. Be using nebulised hypertonic saline concurrently or in the 2 weeks prior to visit 1 5. Have had a significant episode of haemoptysis (>60 mL) in the three months prior to enrolment 6. Have had a myocardial infarction in the three months prior to enrolment 7. Have had a cerebral vascular accident in the three months prior to enrolment 8. Have had major ocular surgery in the three months prior to enrolment 9. Have had major abdominal, chest or brain surgery in the three months prior to enrolment 10. Have a known cerebral, aortic or abdominal aneurysm 11. Be breast feeding or pregnant, or plan to become pregnant while in the study 12. Be using an unreliable form of contraception (female subjects at risk of pregnancy only) 13. Be participating in another investigative drug study, parallel to, or within 4 weeks of study entry 14. Have a known allergy to mannitol 15. Be using beta blockers 16. Have uncontrolled hypertension (systolic BP > 190 and or diastolic BP > 100) 17. Have a condition or be in a situation which in the Investigator's opinion may put the subject at significant risk, may confound results or may interfere significantly with the patient's participation in the study 18. Be Ã¢â‚¬Ëœ Aridol-MTT test positive

Interventions

Product Name: IDPM: Inhaled Dry Powder Mannitol Pharmaceutical Form: Inhalation powder, hard capsule INN or Proposed INN: MANNITOL CAS Number: 69658 Concentration unit: mg. Concentration number: 40-. Pharmaceutical form of the placebo: Inhalation powder, hard capsule Route of administration of the placebo: Inhalation use

Outcome measures

Primary Outcome(s): determine the effects of 400 mg twice-daily administration of IDPM on FEV1 in all patients with CF compared to control. Primary end point(s): Change in absolute FEV1 (forced expiratory volume in 1 second) Secondary Objective: Ã¢â‚¬Â¢ To determine the effects of 400 mg twice-daily administration of IDPM on FEV1 in patients with CF on existing RhDNase treatment compared to control. (key objective) To assess whether IDPM treatment: Reduces pulmonary exacerbations in those taking RhDNase as a sub-group and in the total cohort (key objective); Improves quality of life (key objective); Reduces days on IV antibiotics, rescue oral or inhaled antibiotics; Reduces days in hospital due to pulmonary exacerbations; Improves other measures of lung function; Demonstrates an appropriate safety profile (adverse events, haematology, biochemistry, change in bronchodilator response, sputum microbiology, physical examination); Reduces hospital and community care costs

http://apps.who.int/trialsearch/Trial.aspx?TrialID=EUCTR2006-004078-28-GB

Keywords

bronchitol; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; Mannitol; pharmacological_intervention; Powders; Respiratory System Agents;