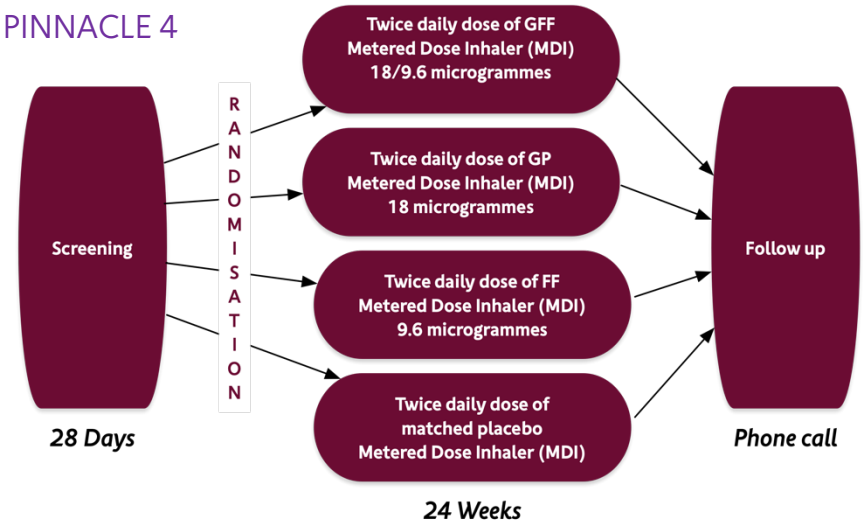
TrialsConnect — PINNACLE 4

Study Summary

One of three Multi-Centre Phase 3 Studies:
PINNACLE 4

Funded by Pearl, a member of the AstraZeneca Group, this clinical study aimed to investigate the efficacy and safety of GFF MDI (Metered Dose Inhaler) compared to its individual components (GP MDI and FF MDI) and a placebo MDI. The inhaler formulations used innovative 'co-suspension delivery technology' and were designed for a population with moderate-to-very severe COPD (Chronic Obstructive Pulmonary Disease), including Asian and European patients.



Comparison of GFF MDI to its singular components, GP (glycopyrrolate) MDI and FF MDI (formoterol fumarate), and a placebo MDI in patients with a low 'forced expiratory volume' measure of lung obstruction (FEV below 0.70).

GFF MDI uses the drugs glycopyrrolate (GP) and formoterol fumarate (FF) combined using technology designed to prevent patient-handling errors. The inhaler provides drug delivery to all regions of the lung with accuracy because a mucus-like outer coating holding the drug is similar to the mucus in the lungs.

Patients were between 40-80 years of age with a clinical history of COPD as defined by the European Respiratory Society. Results from PINNACLE 4 show that breathlessness was reduced by GFF MDI and that there were improved lung function, symptoms, and patient-reported outcomes in patients in Europe, Asia, and the USA.

The study is fully reported at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6167125/