New research method questions traditional efficacy trial model

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Traditional efficacy trials have limited relevance to everyday clinical practice and should be changed, according the authors of a new study into chronic obstructive pulmonary disease (COPD) treatments.

The report (Effectiveness of Fluticasone Furoate-Vilanterol for COPD in Clinical Practice) published today (4 September 2016) in the *New England Journal of Medicine* details a new method of testing effectiveness of drugs which puts the patients' clinical experience at the heart of the process.

Led by Professors Jorgen Vestbo and Ashley Woodcock from The University of Manchester's School of Biological Sciences, the research team conducted an effectiveness and safety trial of fluticasone furoate-vilanterol to manage COPD. Instead of a traditional randomised cohort selected using strict criteria, the new study used specific, representative patients drawn directly from GP practices in which they were receiving care for COPD.

Entitled the Salford Lung Study, the clinical trial recruited 2799 patients with COPD from 75 GP practices in and around Salford in Greater Manchester. The GP practices were involved in ensuring the study not only had access to specific COPD patients but also that the usual clinical care provided by the practices was built into the trials - the study was therefore rooted in a real clinical environment unlike tradition efficacy trial model.

"Our findings challenge the automatic transfer of findings from efficacy studies to clinical guidelines or everyday clinical practice," said Prof Vestbo.

"Involving the GP practices in the Salford Lung Study allowed the team to create an unsupervised environment for the patients, enabling important factors in usual clinical care - such as adherence, frequency of dosing and persistence of good inhaler technique - to rightly influence the trial outcomes.

"This is a major deviation from the traditional model, but one we believe will deliver a more accurate set of results regarding effectiveness and safety of new medicines and treatments."

The trial proved that broad populations of patients with COPD benefit from treatment with a once-daily treatment regimen of combined fluticasone furoate and vilanterol was associated with a lower rate of COPD exacerbations than usual care, without a greater risk of serious adverse events.

The 2799 patients in the study were randomly assigned either a combination of fluticasone furoate at a dose of 100 ?g and vilanterol at a dose of 25 ?g or requested to remain on their usual care regime as identified by their GP. The yearlong study concluded that the fluticasone furoate and vilanterol cohort had an 8.4% less frequent occurrence of moderate to severe exacerbations than the usual care group, leading the team to state that the fluticasone furoate and vilanterol combination was superior to usual COPD care - with no significantly higher risk of serious adverse effects.

Provided by University of Manchester