

WHAT IS A 'DOUBLE-DUMMY' TRIAL?

We continue our series of articles on research concepts by explaining what 'double-dummy' trials are and why researchers use them to compare medications that are delivered using different types of inhalers.

Jane Upton

Research Project Manager, Education for Health

One way pharmaceutical companies evaluate new asthma medications is by comparing them with a similar type of medication (called a 'control') in a randomised controlled trial (see *BJPCN* June 2007, page 109). In this type of trial researchers try to prevent patients knowing if they are receiving the new or control medication as this knowledge might affect patients' behaviour and therefore the findings of the trial (see *BJPCN* September 2007, page 158 and December 2007, page 208 to understand why this might be).

MEDICATION IN THE SAME TYPE OF INHALER

It is not difficult for researchers to conceal this knowledge from patients when both medications are delivered using the same type of asthma inhaler. In this situation, all patients can be given the same type of inhaler; half will contain the new medication, the other half will contain the control medication (Figure 1).

DIFFERENT TYPES OF INHALER

But what if the new asthma medication can only be delivered using a different type of inhaler from the control medication? An example of this is a study which compared beclomethasone/formoterol, the 'new' medication which is delivered using a metered-dose inhaler (MDI) and budesonide/formoterol, the 'control' medication which is delivered in a Turbuhaler®. ¹

To solve this challenge, the researchers included two dummy inhalers, which did not contain any active medication, in the research design alongside an active MDI which contained beclomethasone/formoterol and an active Turbuhaler® which contained budesonide/formoterol.

In the study, subjects were randomly allocated to receive either the new or control medication. Both groups then received an MDI and a Turbuhaler® but with different contents. The group allocated to receive the new medication received this in the MDI but also received a dummy Turbuhaler®. The control group received the active control medication in the Turbuhaler® but the MDI was a dummy inhaler. As all subjects used both types of inhalers they were blinded from knowing which group they were in (Figure 2).

So, in summary, this study used a 'double-blind, double-dummy, randomised two-arm parallel-group controlled study design' to test the hypothesis that the new medication was not inferior to the comparison medication already on the market. If you are unclear on any of these terms, check back with previous articles in this series. The next article in the series will look at the importance of hypotheses in scientific research.

Reference

1. Papi A, Paggiaro PL, Nicolini G, Vignola AM, Fabbri LM. Beclomethasone/formoterol versus budesonide/formoterol combination therapy in asthma. *Eur Respir J* 2007; **29**: 682-689.

Figure 1. Study comparing medications delivered by the same type inhaler

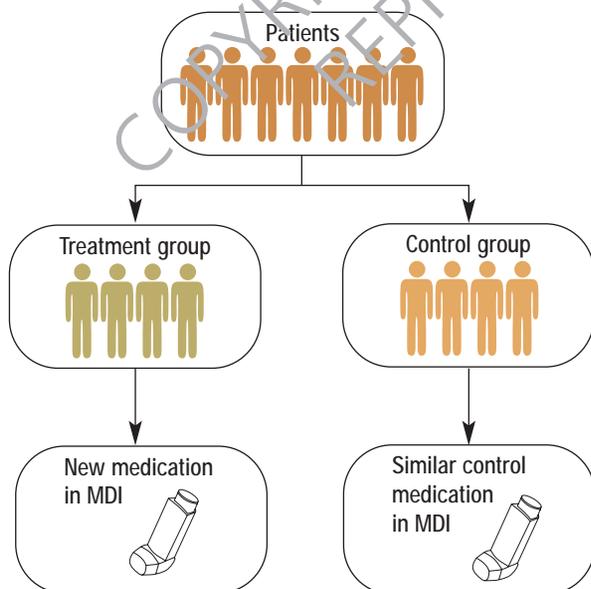


Figure 2. Study comparing medications delivered by different type inhalers

