

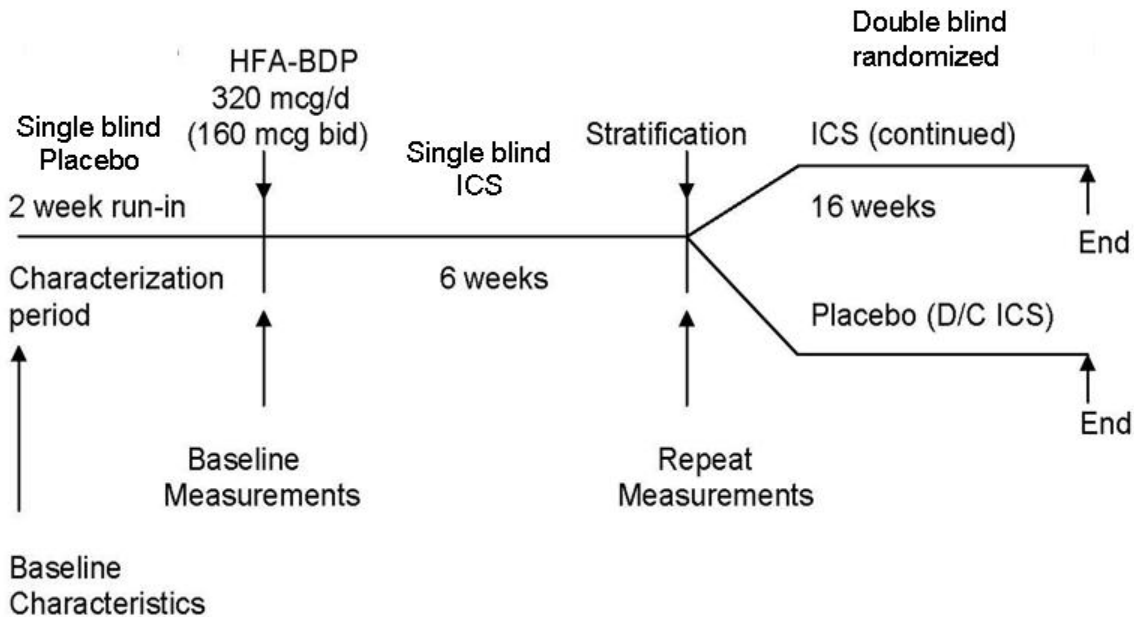
**Asthma Clinical Research Network (ACRN)
Predicting Responses for Inhaled Corticosteroid Efficacy (PRICE)**

NULL HYPOTHESIS

The lack of an ICS response defined by (1) change in FEV₁ and (2) change in PC₂₀ is not correlated with the following baseline biomarkers: (1) bronchodilator response to a beta-2 agonist < 15%; (2) eNO < 15 ppb; (3) sputum eosinophils < 2%; (4) duration of asthma > 10 years.

DESIGN

The PRICE trial enrolled male and female patients, 18-55 years of age, with a history of asthma as indicated by baseline FEV₁ 55-85% of predicted and methacholine PC₂₀ ≤ 12 mg/ml at time of study entry. At the end of the 2-week run-in period, the patients entered a 6-week single-blind period with ICS (beclomethasone dipropionate HFA [HFA-BDP] 160 µg bid), during which biomarkers (bronchodilator response, eNO, sputum eosinophils, duration of asthma), PV curve, and PC₂₀ were measured. Following this, patients were randomized (stratified according to clinical center and good, marginal, and poor FEV₁ responders from the previous 6-week ICS period) in a double-blind manner to continuation with the active ICS or its placebo. Asthma control and exacerbations were the outcome measures for this 16-week period.



RESULTS

Enrollment for PRICE began in June 2003 and the last patient visits occurred in September 2004. There were 83 patients enrolled in the single-blind ICS period. The major publication is under development.