Placebo-Controlled Trial of Cytisine for Smoking Cessation

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ABSTRACT

BACKGROUND
Cytisine, a partial agonist that binds with high affinity to the \( \alpha_4\beta_2 \) nicotinic acetylcholine receptor, is a low-cost treatment that may be effective in aiding smoking cessation. This study assessed the efficacy and safety of cytisine as compared with placebo.

METHODS
We conducted a single-center, randomized, double-blind, placebo-controlled trial. Participants were randomly assigned to receive cytisine or matching placebo for 25 days; participants in both groups received a minimal amount of counseling during the study. The primary outcome measure was sustained, biochemically verified smoking abstinence for 12 months after the end of treatment. Of 1542 adult smokers screened, 740 were enrolled and 370 were randomly assigned to each study group.

RESULTS
The rate of sustained 12-month abstinence was 8.4% (31 participants) in the cytisine group as compared with 2.4% (9 participants) in the placebo group (difference, 6.0 percentage points; 95% confidence interval [CI], 2.7 to 9.2; \( P = 0.001 \)). The 7-day point prevalence for abstinence at the 12-month follow-up was 13.2% in the cytisine group versus 7.3% in the placebo group (\( P = 0.01 \)). Gastrointestinal adverse events were reported more frequently in the cytisine group (difference, 5.7 percentage points; 95% CI, 1.2 to 10.2).

CONCLUSIONS
In this single-center study, cytisine was more effective than placebo for smoking cessation. The lower price of cytisine as compared with that of other pharmacotherapies for smoking cessation may make it an affordable treatment to advance smoking cessation globally. (Funded by the National Prevention Research Initiative and others; Current Controlled Trials number, ISRCTN37568749.)