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Title: Quit smoking with Champix: Parallel, randomised clinical trial of efficacy for the first time in Iran

Dr. Gholamreza 394 Heydari ghrheydari@nritld.ac.ir MD ¹ and Prof. Saeid 395 FallahTafti sfallahtafti@nritld.ac.ir MD ². ¹ Tobacco Control Research Center, National Research Institute of TB & Lung Diseases, Tehran, Islamic Republic of Iran and ² Nursing Research Center, National Research Institute of TB & Lung Diseases, Tehran, Islamic Republic of Iran .

**Body:** Introduction: Smoking cessation programs were first introduced in Iran in 1997 by the National Research Institute of Tuberculosis and Lung Diseases and up to now, various nicotine replacement therapies have been prescribed. The aim of this study was to evaluate effectiveness of Varenicline for tobacco cessation in this country and compare it with other measures. Materials and Methods: This was a randomized parallel clinical study during 2009-2010. Participants were divided into three parallel groups randomly. The first group received brief counseling on cessation. The second group received nicotine patches 15 mg/daily for 8 weeks and the third group was prescribed Varenicline one 0.5 mg pill daily for the first 3 days, followed by 0.5 mg twice a day for 4 days and subsequently 1 mg twice daily for 8 weeks. Results: The study had 272 participants including 160 men (58.8%). Ninety one people were in the first group, 92 individuals in the second and 89 in the third group. At the end of the first month, 128 people from total (47.1%) succeeded in quitting; this included 17 individuals (18.7%) in the first group, 60 (65.2%) in the second group and 51 (57.3%) in the third group (P=0.000). Follow up at 6 month and a year showed 111 people of total (40.8%) and 58 individual (21.3%) remained smoke free which included 12 (13.2%) and 6 (6.6%) in the first group, 47 (51.1%) and 23 (25%) in the second group and 52 (58.4%) and 29(32.6%) in the third group respectively (P=0.000). Conclusion: Drug treatment can improve success in guitting several fold. Success with Varenicline is slightly better from nicotine replacement treatment.