

## **Publication**

A meta-research study revealed several challenges in obtaining placebos for investigator-initiated drug trials

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OBJECTIVES: To systematically assess the kind of placebos used in investigator-initiated randomized controlled trials (RCTs), where they are obtained, and what hurdles exist in obtaining them. STUDY DE-SIGN AND SETTING: PubMed was searched for recently published non-commercial, placebo-controlled randomized drug trials. Corresponding authors were invited to participate in an online survey. RESULTS: From 423 eligible articles, 109 (26%) corresponding authors (partially) participated. Twenty-one of 102 (21%) authors reported that the placebos used were not matching (correctly labelled in only 1 publication). The main sources in obtaining placebos were hospital pharmacies (32 of 107; 30%) and the manufacturer of the study drug (28 of 107; 26%). RCTs with a hypothesis in the interest of the manufacturer of the study drug were more likely to have obtained placebos from the drug manufacturer (18 of 49; 37% vs. 5 of 29; 17%). Median costs for placebos and packaging was 58,286 US\$(IQR 2,428-160,770 US\$; n=24) accounting for a median of 10.3% of the overall trial budget. CONCLUSION: Although using matching placebos is widely accepted as a basic practice in RCTs, there seems to be no standard source to acquire them. Obtaining placebos requires substantial resources and using non-matching placebos is common.

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