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Controlled Clinical Trial Methods Find Exp Clin Pharmacol. 2010 Mar;32(2):129-32. doi: 10.1358/mf.2010.32.2.1423881.

# A controlled clinical trial to evaluate the effect of GanedenBC(30) on immunological markers

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## Abstract

GanedenBC(30), a probiotic, has been shown to significantly increase T-cell production of TNF-alpha after ex vivo exposure to a strain of adenovirus (AdenoVI) or influenza A (H3N2 Texas strain [FluTex]). The current controlled study was designed to further evaluate the effect of GanedenBC(30) on immunological marker levels following viral exposure. Ten healthy subjects' baseline immunological marker levels were analyzed. Subjects consumed 1 capsule/day of GanedenBC(30) for 28 days and returned for post-treatment immunological marker evaluation. Subjects' baseline measurements served as their own control. All subjects completed the study with no adverse events; however, one subject was excluded from the final analysis based on a reasonable consideration as an outlier. CD3+CD69+ cells, IL-6, IL-8, interferon-gamma (IFN-gamma) and TNF-alpha levels were increased after exposure to AdenoVI and FluTex. IL-1beta levels also increased after exposure to AdenoVI but were decreased after ex vivo exposure to FluTex. CD3+CD69+ cells increased significantly (P = 0.023) after exposure to both viral strains. Differences in IL-8 levels after FluTex exposure achieved statistical significance (P = 0.039) as did IFN-gamma levels after AdenoVI exposure (P = 0.039). A regimen of one capsule per day containing 500 million CFU of GanedenBC30 may be a safe and effective option for enhancing the immunological response to common viral respiratory tract infections.

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