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**The effectiveness of lactase enzyme in management of subjects with
adult-type hypolactasia:
randomized placebo-control double-blind cross-over trial**

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ABSTRACT

Background: Adult-type hypolactasia is the most common enzyme deficiency in human which is characterized by the down regulation of lactase enzyme activity in the intestine. The most common gastrointestinal (GI) symptoms which characterize intolerance to lactose are flatulence, diarrhea, gurgling, abdominal distension and abdominal cramping. The hypolactasia needs to be corrected in all cases when gastrointestinal symptoms interfere patient's life and activity. The one of the ways to manage lactose intolerance is supplementation with lactase enzyme.

Aims: to estimate the effectiveness of lactase enzyme in management of subjects with adult-type hypolactasia by double-blind randomized placebo- controlled trial cross-over.

Methods: Randomized placebo-control double-blind cross-over 2x2 trial. The study sample includes the 68 students from Northern State Medical University (NSMU) at the age 18 to 28 years. All subjects were previously undergone genotyping for detection lactase persistent-non-persistent genotype. The intervention consisted in 500 ml of milk together with 2 capsules (lactase enzyme or placebo) that was given in a randomized manner with similarly repeated intervention after one week wash-out period by the load of another 2 capsules together with milk. Logistic regression analysis was used to study the association between the lactase enzyme intervention and occurrence of symptoms. McNemar

test was used to compare the occurrence of symptoms in each group before and after intervention. Mann-Whitney U test was used to compare the groups with lactase enzyme and placebo during the first intervention period, and Wilcoxon signed rank test was used to compare the interventions using the both intervention periods.

Results: The study showed that effect of lactase enzyme taking together with milk indigestion by people with adult-type hypolactasia dose not differ on placebo effect

Key words: adult-type hypolactasia, lactose intolerance, lactase enzyme, gastrointestinal symptoms, randomized control trial