Randomized Controlled Trial

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Randomized double blind clinical trial evaluating the Ellagic acid effects on insulin resistance, oxidative stress and sex hormones levels in women with polycystic ovarian syndrome

Mahnaz Kazemi¹, Fatemeh Lalooha², Mohammadreza Rashidi Nooshabadi³, Fariba Dashti¹, Maria Kavianpour^{#4}, Hossein Khadem Haghighian^{#56}

Affiliations

- Department of Nutrition, School of Health, Qazvin University of Medical Sciences, Qazvin, Iran.
- ²Department of Obstetrics and Gynecology, Faculty of Medicine, Qazvin University of Medical Sciences, Qazvin, Iran.
- ³Department of Pharmacology, School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.
- ⁴Department of Applied Cell Sciences, School of Advanced Technologies in Medicine, Tehran University of Medical Sciences, Tehran, Iran. Kavianpour.maria@gmail.com.
- Metabolic Diseases Research Center, Research Institute for Prevention of Non-Communicable Diseases, Qazvin University of Medical Sciences, Qazvin, Iran. khademnut@yahoo.com.
- Department of Nutrition, Faculty of Health Qazvin, University of Medical Sciences, Qazvin, Iran. khademnut@yahoo.com.

 *Contributed equally.

Abstract

Objective: The design of this study was due to the report of the antioxidant properties of Ellagic acid (EA) for its evaluation on the Insulin resistance (IR), oxidative stress and sex hormones levels in women with polycystic ovarian syndrome (PCOS).

Methods: In this randomized, double-blind, placebo-controlled clinical trial, 60 patients were recruited. Patients were randomly allocated consumed a capsule containing 200 mg of EA per day (n = 30) or placebo (n = 30) for 8 weeks. The fasting blood sugar (FBS), insulin, IR, total cholesterol (TC), triglycerides (TG), low density lipoprotein (LDL), high density lipoprotein (HDL), total antioxidant capacity (TAC), Malondialdehyde

(MDA), C-reactive protein (CRP), Tumor necrosis factor-alpha (TNF- α), sex hormones and anti-mullerian hormone (AMH) were measured at the beginning and end of the study.

Result: At the end of the study, the mean of FBS, insulin, IR, TC, TG, LDL, MDA, CRP, TNF- α , total testosterone, prolactin and AMH were significantly decreased in the intervention group compared to the placebo group (P < 0.05). Also, there was a significant increase in the mean of TAC after supplementation with EA (P < 0.05). At the end of the study, no significant changes were observed in the mean of anthropometric factors, physical activity and food intake (P > 0.05).

Conclusion: EA supplementation can be helpful as a diet supplement in women with PCOS through improvement in insulin resistance. This supplement may be used to reduce metabolic disorders in women.

Trial registration: This study was retrospectively (07-07-2019) registered in the Iranian website (www.irct.ir) for registration of clinical trials (IRCT20141025019669N12).

Keywords: Anti-mullerian hormone; Ellagic acid; Insulin resistance; Polycystic ovarian syndrome; Stress oxidative.