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Efficacy and safety of three Ayurveda decoctions for polycystic ovary syndrome: A randomized, single-blind, three-arm, clinical trial - Study protocol

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Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine abnormalities in women of reproductive age. Due to fear of side effects of allopathic medicines some patients prefer to take Ayurveda treatment for PCOS. Ayurveda treatment for this condition is widely practiced in Sri Lanka. However, most drugs are not clinically tested for efficacy and safety. Therefore, the aim of this research is to detect the efficacy and safety of three Ayurveda decoctions (decoction of *Nigella sativa*, decoction of *Sesamum indicum* and decoction of *Nigella sativa* and *Sesamum indicum*) used for PCOS. The study would be conducted as a randomized, single blind, three arm, comparative clinical trial. This study will be conducted in the National Ayurveda Teaching Hospital, Borella and the Rotterdam (2003) diagnostic criteria will be used to diagnose PCOS. Selection of participants will be done according to the inclusion and exclusion criteria and allocated randomly into three arms. Participants of Arm I, Arm II and Arm III will receive an oral drug for twelve weeks and will be followed up for 3 months after the administration of the drug. Each patient will undergo hematological and biochemical investigations before and after the interventions. Transabdominal sonography or transvaginal sonography will be carried out before and after the treatment and during the follow up period as a primary outcome measure. Symptom severity and their impact on quality of life will be assessed at the beginning and at end of the treatment by PCOS symptoms and Health Related Quality of Life Questionnaire. Body constituent (Prakriti) is identified by screening with the help of a validated questionnaire at the beginning and end of the study. Association between constituents and PCOS will be evaluated at the beginning and end of therapy. Data will be analyzed using Wilcoxon sign rank test and Mann-Whitney U test. At the end of this clinical research, the effectivity of Ayurveda treatment for PCOS could be presented. Furthermore, it would result in evidence-based scientific data on classical Ayurveda treatment.

Keywords: Ayurveda, Polycystic Ovary Syndrome, *Nigella sativa*, *Sesamum indicum*

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