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The Efficacy of a Traditional Sri Lankan Medicine Formula on Endometriosis: A study protocol for a randomized single-blind, active comparator clinical trial.

¹Kaumadi Karunagoda, ²*Pathirage Kamal Perera,

¹Department of Ayurveda Surgery, ENT, Ophthalmology and Gynecology, Obstetrics and Pediatrics, Faculty of Indigenous Medicine, University of Colombo, Rajagiriya, Sri Lanka

²Department of Ayurveda Pharmacology, Pharmaceutics and Community Medicine, Faculty of Indigenous Medicine, University of Colombo, Rajagiriya, Sri Lanka

Abstract

Background - According to the WHO data sheet, endometriosis affects approximately 10% (190 million) of reproductive-age women and girls worldwide. Endometriosis has no known cure; thus, treatment focuses on symptom management. Ayurveda treatment for this condition is being practiced in Sri Lanka. Significant numbers of cases were successes with Ayurveda treatment and it was noticed that this herbal formula controlled symptoms associated with endometriosis.

This study is aimed to explore the efficacy and safety of the currently available Sri Lankan Traditional Formula on Endometriosis comparisons to a control group.

Method - The study was designed as a randomized, single-blind, comparative clinical study with 30 participants in each arm. Participants diagnosed with Endometriosis who meet the inclusion criteria are selected to participate in this study. One arm undergoes a Sri Lankan Ayurveda formula for eight weeks and an allopathic drug treats the other arm. The primary efficacy outcome is a change in endometriosis-related pelvic pain from baseline to study end measured on a visual analog scale (VAS), covering a recall period of 4 weeks. Secondary efficacy outcomes are based on the physician-assessed modified Bib Eroglu and Berman (B&B) severity profile. Quality of life will be assessed at screening and study end using the Short Form-36 (SF-36) Health Survey.

The haematological investigations include FBC, AST/ALT, and Serum Creatinine/GFR, Urine full report (UFR) will be carried out before and after the treatment as safety parameters. Statistical analysis will be done using SPSS version 16. All statistical tests will be performed, two-tailed with significance determined by the reference to the 5% level. The major outcome of this study will compare the effectiveness and safety of Ayurveda formulas in the hope of providing significant evidence for using Ayurveda medicine for endometriosis.

Key words - Endometriosis, Sri Lankan Traditional Formula, Clinical trial