

Category 1 (A)



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Peradeniya University

International Research Sessions

2015

Volume 19

5th and 6th November 2015

Abstract No. 250 (Poster)

A SAFETY STUDY ON A NOVEL AYURVEDIC PREPARATION, SUDARSHANA SUSPENSION, IN HEALTHY ADULT VOLUNTEERS

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Sudarshana powder (SP) is a very effective anti pyretic Ayurvedic preparation extensively used in Sri Lanka as well as India. This contains 53 ingredients with *Andrographis paniculata* (Burm. F.) Nees as the main component (50%). The extreme bitterness of this powder reduces the patient compliance and administration to children is difficult. Therefore this powder was developed into a user-friendly standard Ayurveda suspension. The aim of this present study was to evaluate the safety of the novel formulation, Sudarshana Suspension (SS) in a group of healthy adult volunteers.

Following ethical clearance, 35 healthy volunteers of both sexes were selected by open advertisement. Written consent was obtained from the participants and enrolling in to the study and the information sheet and a diary for record keeping were explained to the participants in their own language. Sudarshana Suspension was prepared at the pharmacy of the Institute of Indigenous Medicine, University of Colombo and the study was carried out in Department of Biochemistry, Faculty of Medical Sciences, University of Sri Jayewardenepura.

Acute effects of S. Suspension were tested by measuring the alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (γ -GT), alkaline phosphatase, haemoglobin content (Hb), urea and serum creatinine to determine liver and kidney functions.

Healthy volunteers were given four doses of Sudarshana Suspension at six hourly intervals per day for 7 consecutive days. Dosage of drug was determined according to the body weight of the volunteer. A 3ml of blood sample was drawn on Day 0, Day 3 and Day 8. The liver and kidney function markers (ALT, ALP, AST, γ -GT, Creatinine and Urea) were analyzed an automatic biochemical analyzer (Kone) and serum Hb was analyzed by the spectrophotometer.

There were no significant differences ($p > 0.05$) in serum levels of ALT, AST, ALP, γ -GT, urea, creatinine and Hb in Day 3 and Day 8 when compared to the Day 0 (base line) values. Healthy volunteers did not report any adverse effects, such as vomiting, headache, diarrhoea, or any other abnormal feelings during the treatment period and also the follow up period.

Therefore from the findings of this study, it can be concluded that, the novel preparation Sudarshana Suspension does not cause any significant acute effects on liver or renal functions in healthy adults.

Financial assistance given by Human Resource Development Program-HETC project (CMB/N) is acknowledged.