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Evaluation of SENSORIL®-Withania somnifera - on biomarkers and mental stress test induced cardiovascular changes in healthy human participants

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Introduction: Stress is the body's reaction to a change that requires a physical, mental or emotional adjustment or response. Mental stress has been recognized as an independent coronary risk factor. Antioxidants have been helpful in reducing symptoms such as fatigue, stress and anxiety. Withania Somnifera (SENSORIL®) possesses anti-inflammatory, antitumor, anti-stress, antioxidant properties. This study aims to evaluate the effects of SENSORIL® on mental stress induced changes in cardiovascular pharmacodynamic parameters, aortic wave reflections and Biomarkers in healthy human participants.

Methodology: After written informed consent to IEC approved study, 20 healthy male subjects were randomized to receive either SENSORIL® 250mg (2 capsules) or matching placebo 2 capsules twice daily for 14 days. Participants performed tests of psychomotor performance thrice during which stress was induced by playing a metronome loudly with headphones in place which acted as distracter. Augmentation index and augmented pressure of the central pressure waveform were measured before and after the above procedure. The participant then received medication for 14 days and same procedure repeated after 3 hrs of drug administration. Washout period was for 10-14 days and same method repeated with other drug. ADR reported was recorded. Blood samples were collected for assessing biomarkers and safety parameters.

Results: Compared to baseline and placebo treatment, SENSORIL® produced a statistically significant decrease in mean aortic pressure, augmentation index and sub endocardial variability ratio. Both radial and aortic SBP were decreased significantly. SENSORIL® significantly decreased hs-CRP values from 1.02 + 0.96mg/L to 0.63 + 0.56 mg/L. ($p<0.05$). Malondialdehyde (MDA) levels showed a marked decrease from 5.07+0.62 to 4.45+0.55nmol/ml with SENSORIL® ($p<0.01$). Normal range of MDA is 2.7-4.5nmol/ml. Similar changes were noted with other biomarkers of oxidative stress. Both treatments were well tolerated.

Conclusion: SENSORIL® decreased the mental stress induced changes on aortic wave reflections, suggesting the beneficial effects of this formulation in reducing cardiovascular pharmacodynamic effects of mental stress probably by reducing the oxidative stress. There were no serious adverse vents reported. Further studies are required to confirm the therapeutic role of SENSORIL® in patients with post traumatic stress and other anxiety disorders.

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Biography

Pingali Usharani has completed MD in pharmacology and later DNB in Clinical Pharmacology in 1993. Joined as faculty in NIMS, superspeciality hospital in 1996. Presently working as Additional Professor. Trained in GCP and Bioethics. Published about 80 clinical research papers in national and international journals. Edited a book in Clinical research and contributed about 36 chapters in text books. Editorial Board Member of Indian Journal of Pharmacology. Presented more than 50 papers in scientific meetings and delivered guest lectures on Clinical research topics in national and international meetings. Teacher and guide to DM Clinical Pharmacology and PhD students.

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