A SAFETY EVALUATION AND TOLERABILITY OF SMRUTIHILLS CAPSULE AN AYURVEDA FORMULATION IN HEALTHY SUBJECTS.

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ABSTRACT

Background: Due to stressful & sedentary lifestyle, unhealthy and unhygienic food habits many peoples develop lifestyle disorders which effects on body as well as mind. Every year in India prevalence rate of age associated with memory impairment was 3.6% individuals of 40 years and above. Ayurveda had described many natural memory boosting drugs which helps in increasing the memory and relieves stress. Medhya (Memory boosting) drugs i.e., Shankhpushpi, Mandukparnee, Guduchi, Brahmi, Jyotishmati, Vacha etc. promising results in increasement of cognitive functions available in Ayurveda texts. Smritihills capsule is made from the combination of such drugs. Objectives: The aim of the study was safety evaluation and tolerability of Smrutihills capsule on total clinical fitness, hematological and biochemical parameters in healthy individuals assessed on MOCA Test (Montreal Cognitive Assessment). Materials and methods: Present study was an observational clinical study conducted on 30 healthy volunteers. 2 capsules of Smrutihills capsules (500 mg) twice a day for 21 days were given to the 30 healthy volunteers. The data was assessed on clinical cognitive functions and total MOCA score. Results: The average total score of MOCA test increased significantly from 24.74 ± 3.26 to 26.47 ± 1.17 after 21st day treatment with Smrutihills Capsule as t=2.7358 and p value 0.0082. Thus, all the cognitive functions were increased significantly from baseline to completion of the treatment in healthy volunteers (P<0.05). Conclusions: Smrutihills capsule has been put to critical safety tests in healthy volunteers and found to be devoid of any adverse effects. It provides good clinical evidence to prove the efficacy and safety of Smrutihills capsule in healthy volunteers.

Keywords: Memory, MOCA score, Smruti, Smrutihills Capsule.

1. INTRODUCTION

Due to stressful & sedentary lifestyle, unhealthy and unhygienic food habits many peoples develops lifestyle disorders which effects on body as well as mind. Ayurveda has unique concept about the diseases, it considers the involvement of soma and psyche in pathogenesis of disease. Physical (Stable body) and Psychological (stable mind) was important for healthy life. In India, the prevalence rate of association of age with memory impairment was 3.6% individuals of 40 years and above.1 Ayurveda has memory like concepts explained in classical texts as Smruti (memory), Dhi (Intelligence), Drhuti and Buddhi (intellect). Smruti is remembrance of the things which are previously experience of person through perception in mind, seen by eyes, heard with ears.2 Ayurveda had described many natural memory boosting drugs which helps in increasing the memory, relieves stress. Smritihills capsules were an ayurvedic combination of natural
memory boosting drugs. Smrutihills Capsule is an ayurvedic proprietary formulation of many herbal drugs having properties improves concentration, antistress, memory stimulant, revitalizing, brain tonic, releasing anxiety, immunomodulator. Primary objective of the present study was safety evaluation and tolerability of Smrutihills capsule on total clinical fitness, hematological and biochemical parameters in healthy volunteers.

2. MATERIALS AND METHODS
It was an observational, non-comparative, prospective trial. The trial protocol and related documents were made and approved by the Institutional Ethics committee (IEC) and Indian Council of Medical Research (ICMR) ethical guidelines.

2.1. Primary Objectives
Primary outcome measure of study was to evaluate the safety and tolerability of Smrutihills capsule in healthy individuals on total clinical fitness, hematological and biochemical parameters in healthy individuals by assessing change in MOCA (Montreal Cognitive Assessment) total score.

2.2. Trial interventions
2 capsules of Smrutihills capsules (500 mg) twice a day for 21 days were used in this study. The trial drugs were made from GMP certified company.

2.3. Inclusion criteria
- Either gender
- Healthy volunteers
- Subjects with age group between 18 years to 60 years.
- Health of the subject should be examined by Physician with medical certificate of good health.

2.4. Exclusion Criteria
- Subjects with systemic diseases.
- Patient not willing to come regular follow up for entire duration of study.

2.5. Withdrawal criteria
In the present study, all subjects were free to withdraw from the trial at any time without the permission of investigator or any reason. No withdrawal was seen in present study.

2.6. Study procedures
Thirty healthy individuals of having either sex and aged between 18 years to 60 years and with body weight in accordance with LIC table were included for the present study. Each subject underwent through physical examination. Upon confirming the clinical fitness of the subjects, they were assigned a number and their informed written consent obtained. After checking the baseline parameters (pulse rate and blood pressure) blood sample were collected for hematological and biochemical test done. 2 capsules of Smrutihills capsule (500 mg) twice a day was given to the volunteers for 21 days. The volunteers were followed up every day in the morning to check if there were any adverse effects or intolerance during the treatment period. On 21st day, blood samples were collected from subjects to carry out the same set of investigations as performed earlier. MOCA test (Montreal Cognitive Assessment) was used to assess parameters i.e. orientation, fluency, immediate recall, late recall, calculation, abstraction, visuoperception, attention in healthy volunteers. MOCA test is having 30 questions with scoring from 0 to 30, which helps to access the cognitive functions of volunteers. Case report forms are made and completed.

2.7. Follow-up assessment
End point evaluation visits were made at baseline and at 21 days. MOCA total Score were recorded during starting and ending day follow up of subjects.

2.8. Adverse drug reaction (ADR)
Any Adverse Drug Reaction or event observed during treatment period if any, that were documented and its proper management were done at particular time and also recorded in the
CRFs. No any adverse drug reaction seen in the present study.

2.9. Drug Review (Table No. 1)

2.10. Statistical analysis

The values are expressed as Mean ± SD or SE or mean with range or median. The results were analyzed statistically using Paired student’s ‘T’ test. The minimum level of significance was fixed at 5% level (p < 0.05).

3. RESULTS

The present study was conducted on 30 healthy volunteers. Out of these, all have completed the study. There were no drop outs and all volunteers complied well during the trial period. Hematological and Biochemical test done on day 21st following Smrutihills capsule administrations were within normal and comparable with baseline values (day 0). No adverse effects were observed in any of the cases. The capsule showed significant improvement in the cognitive functions of healthy volunteers.

At baseline visit, on Montreal Cognitive Test (MOCA) assessed the total score was 24.74 ± 3.26. The average total score of MOCA test increased significantly from 24.74 ± 3.26 to 26.47 ± 1.17 after 21st day treatment with Smrutihills Capsule as t=2.7358 and p value 0.0082.[as shown in Fig. No. 1].

Table No. 1. Contents of Smrutihills Capsule

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Drug</th>
<th>Latin Name</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mandukparnee Whole Plant(^a)</td>
<td>Centella Asiatica</td>
<td>129.05 mg</td>
</tr>
<tr>
<td>2</td>
<td>Guduchi Stem(^4)</td>
<td>Tinospora Cordifolia</td>
<td>64.50 mg</td>
</tr>
<tr>
<td>3</td>
<td>Brahmi Whole Plant(^5)</td>
<td>Bacopa Monniera</td>
<td>193.55 mg</td>
</tr>
<tr>
<td>4</td>
<td>Jyotishmati Seed(^6)</td>
<td>Celastrus Paniculatus</td>
<td>32.25 mg</td>
</tr>
<tr>
<td>5</td>
<td>Vacha Rhizome(^7)</td>
<td>Acorus Calamus</td>
<td>16.15 mg</td>
</tr>
<tr>
<td>6</td>
<td>Shankhapushpi Leaf(^8)</td>
<td>Evolvulus Alsinoides</td>
<td>64.50 mg</td>
</tr>
<tr>
<td>7</td>
<td>Go Ghrit(^9)</td>
<td>Cow Ghee</td>
<td>500 mg</td>
</tr>
<tr>
<td>8</td>
<td>Go Dugdha(^10)</td>
<td>Cow Milk</td>
<td>500 mg</td>
</tr>
</tbody>
</table>

Figure No. 1. Average of MOCA test score before and after Smrutihill capsule administered
4. DISCUSSION

Primary objectives of study were to evaluate the safety evaluation and tolerability of Smrutihills capsule on total clinical fitness, hematological and biochemical parameters in healthy volunteers by assessing change in MOCA total Score. The healthy volunteers were selected accordingly to assessment criteria. For the safety evaluation of Smrutihills capsule on the total clinical fitness, hematological and biochemical parameters in healthy volunteers assessed on MOCA. Statistically significant (p<0.05) results are seen in the study. Average total MOCA test score of healthy volunteers was assessed on before and after study shows that significantly increased. Findings show that Smrutihill Capsule an Ayurvedic proprietary drug had a significant result in improvement of cognitive functions of healthy volunteers.

Composition of Smrutihills Capsule is collectively having Vata shamaka properties and helps to reduce stress, anxiety & improves intelligence power of retention & memory. Ayurvedic Memory Booster Smrutihills has the revitalizing & memory stimulant properties of Brahmi, Jyotishmati, Mandukparni may help revitalize the nerve and brain cells. May helps to enhance memory, concentration and intelligence. Antistress & immuno-stimulant properties of Shankhpushpi and Guduchi may help reduce stress, anxiety & improves intelligence power of retention and memory. Cow Ghee was useful to increase Dhi (intelligence) and thus it also improves Smruti (memory). Overall all the ingredients are Vata shamak, improving power of cognition.

5. CONCLUSION

It is concluded that Smritihills capsule was statistically effective in Healthy Volunteers in all parameters for taking study. So, the effectiveness and safety of Smritihills capsule in Healthy Volunteers was safe and effective.

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Conflicts of interest: In the present trial of drug, all the authors have no competing interest.

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