A SAFETY EVALUATION AND TOLERABILITY OF ARTHOHIllS CAPSULE AN AYURVEDA FORMULATION IN OSTEOARTHRITIS SUBJECTS.

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ABSTRACT

Background: Osteoarthritis (OA) also a similar clinical manifestation in Ayurveda as Sandhivata is a chronic degenerative disorder. Ayurveda medicine had very good potential for Osteoarthritis (OA) patients. Ayurveda would provide significantly better results comparatively than any medication in alternative medical streams. Objectives: The aim of the study was to evaluate the safety and tolerability of Arthohills capsule on total clinical fitness, hematological and X-ray parameters in osteoarthritis subjects assessed on VAS (Visual analogue scale) and WOMAC Osteoarthritis Index (Western Ontario and McMaster Universities). Materials and methods: It was an observational clinical study conducted on 30 subjects of Osteoarthritis (OA). 2 capsules of Arthohills capsules (500 mg) twice a day for 21 days were given to the 30 volunteers. The data was assessed on clinical symptoms, VAS and WOMAC score. Results: At baseline visit, on Visual Analogue Scale (VAS) assessed the average joint (knee) pain score was 40.28 ± 4.78. The average joint pain (knee) score (VAS) reduced significantly from 40.28 ± 4.78 to 34.77 after 7th day treatment with Arthohills Capsule. The mean total WOMAC score at the baseline visit was 48.21 ± 1.123 to 27.12 ± 2.142 after completion of the study which was reduced significantly. Thus all the parameters and clinical symptoms were reduced significantly from baseline to completion of the treatment in OA subjects (P<0.001). Conclusions: Arthohills capsule has been put to critical safety tests in Osteoarthritis subjects and found to be devoid of any adverse effects. It provides good clinical evidence to prove the efficacy and safety of Arthohills capsule in OA subjects.

Keywords: Arthohills Capsule, Osteoarthritis, Sandhivata, VAS, WOMAC score.

1. INTRODUCTION

Osteoarthritis (OA) is one of the most common chronic rheumatological diseases having with prevalence of 22%-39% in India. Knee Osteoarthritis prevalence increases with the age, so that most of the geriatric subjects have symptoms due to knee OA.4 It had multifactorial etiology characterized by marginal hypertrophy of bone, loss of articular cartilages due to old ages as well as may be due to the subchondral sclerosis. Morphological and biochemical alterations in the synovial membrane of joints and certain pathological changes i.e. ulceration, softening and may be due to the focal disintegration of the articular cartilage in joints. It shows mainly clinical symptoms often are having pain, specifically after prolonged activity as well as weight bearing, and stiffness was experienced after inactivity of joints. Many foreign institutes suggest non-drug treatments i.e., the education of the patients, physical exercises, social support and weight loss mechanism.2 NSAIDs are used as primary care in the starting phases of treatment as analgesic, anti-inflammatory role by inhibiting the synthesis of prostaglandins in the body but having many side effects i.e., renal failure, GI bleeding and

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may be a myocardial infarction at later. At the end stage for pain relief treatment patients may choose a knee replacement therapy as a last option but its cost was out of range for lower economical families. So many countries are using alternative medicine and therapies. Medicinal herbs provide quite better results for pain relief. A

Ayurveda literatures had similar clinical manifestations as ‘Sandhivata’. Causative factors i.e. unhealthy diet, sedentary lifestyle and old age leading to Dhatuksaya which in turns aggravates the Vata Dosha that brings Rukshata, Laghuta, Kharata mostly in the Sandhi (Joints) region. Vata Dosha had responsible for all bodily functions and movements. Sandhivata had features as Sandhi shola (pain), Sandhi Shotha (Swelling), Sthabadha (Stiffness), Atopa (Crepitus). Primary objective of the present study was to evaluate the safety and tolerability of Arthohills capsule in total clinical fitness, hematological and X-ray parameters in osteoarthritis subjects. 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 Arthohills capsule in OA subjects on total clinical fitness, hematological and X-ray parameters in osteoarthritis subjects by assessing change in WOMAC total Score and VAS for pain (visual analogue scale).

2.2. Trial interventions

2 capsules of Arthohills 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
- Age – 40-70
- Diagnosis of OA based on following criteria
  - Typical history of Osteoarthritis
  - Clinical examinations findings
  - Classical radiological findings – X-Ray
- VAS - pain visual analogue score (VAS) were ≥ 4 cm in one or both the knees, while performing a weight bearing activity (e.g., walking, while climbing staircase and standing position) during the preceding 24 hours
- Patients who were taking analgesic or NSAID for pain relief and/or not got satisfied with ongoing treatment and seeking a change.

2.4. Exclusion criteria

- Pregnant and Lactating woman
- Subjects who had non degenerative joint disease or other joint disease which would be interfering with the evaluation of OA,
- Subjects having severe disabling arthritis,
- Subjects having H/o- intra articular knee injection within a month preceding study
- Evidence of severe renal, hepatic, haemopoietic, cardiac disorder,
- patients taking analgesics, tranquilizers, antipyretics and hypnotics or taking excessive alcohol, or any other drug which would be interfering with pain perception and subjects who need for other treatment therapy for OA, except Paracetamol (allowed as a rescue drug during the study period),
- 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 withdrawn from the trial at any time without the permission of investigator or any reason. No withdrawal was seen in the study.

2.6. Study procedures

Thirty osteoarthritis subjects of having either sex and aged between 40 years to 70 years and with body weight in accordance with LIC table were included for the present study. Each sub-
ject 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 x-ray knee joint done. 2 capsules of Arthohills 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 and X-ray repeated to carry out the same set of investigations as performed earlier. Patients recorded the maximum pain which was experienced in both knees on VAS from 0 to 10 scales during the weight bearing activity i.e. walking, while climbing staircase and standing position. WOMAC questionnaire was used to assess parameters i.e., pain, functional ability and stiffness in the subjects of OA knees. Case report forms are made and completed.

2.7. Follow-up assessment

End point evaluation visits were made at base-line and at visits on 0, 7, 14 and 21 days. WOMAC index score and Active pain (VAS) on weight bearing were recorded during every 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 subjects of OA. Out of these, all have completed the study. There were no drop outs and all subjects complied well during the trial period. Hematological and X-Ray test done on day 21st

### Table No. 1. Contents of Arthohills 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><em>Sunthee Rhizome</em>5,6</td>
<td><em>Zinziber Officinalae</em></td>
<td>22.75 mg</td>
</tr>
<tr>
<td>2</td>
<td><em>Shallaki Gum Resin</em>7,8</td>
<td><em>Boswellia Serrata</em></td>
<td>45.45 mg</td>
</tr>
<tr>
<td>3</td>
<td><em>Shuddha Guggul Gum Resin</em>9,10</td>
<td><em>Balsamodendron Mukul</em></td>
<td>45.45 mg</td>
</tr>
<tr>
<td>4</td>
<td><em>Shuddha Laksha Gum Resin</em>11</td>
<td><em>Laccifer Lacca</em></td>
<td>45.45 mg</td>
</tr>
<tr>
<td>5</td>
<td><em>Nirgunde Whole Plant</em>12,15</td>
<td><em>Vitex Negundo</em></td>
<td>45.45 mg</td>
</tr>
<tr>
<td>6</td>
<td><em>Methi Seeds</em>14,15</td>
<td><em>Trigonella Foenum Graceum</em></td>
<td>45.45 mg</td>
</tr>
<tr>
<td>7</td>
<td><em>Asthishrunkhala Stem</em>16,17</td>
<td><em>Vitis Quandragularis</em></td>
<td>45.45 mg</td>
</tr>
<tr>
<td>8</td>
<td><em>Maharasnadi</em>18</td>
<td><em>Generic Preparation</em></td>
<td>90.90 mg</td>
</tr>
<tr>
<td>9</td>
<td><em>Dashmooladi</em>19</td>
<td><em>Generic Preparation</em></td>
<td>90.90 mg</td>
</tr>
<tr>
<td>10</td>
<td><em>Chopchinee Root</em>20,21</td>
<td><em>Rheum Emodii</em></td>
<td>22.75 mg</td>
</tr>
<tr>
<td>11</td>
<td><em>Go Ghrit</em>22</td>
<td>Cow Ghee</td>
<td>500 mg</td>
</tr>
<tr>
<td>12</td>
<td><em>Go Dugdha</em>23</td>
<td>Cow Milk</td>
<td>500 mg</td>
</tr>
</tbody>
</table>
following Arthohills capsule administrations were within normal and comparable with baseline values (day 0). No adverse effects were observed in any of the cases.

At baseline visit, on Visual Analogue Scale (VAS) assessed the average joint (knee) pain score was 40.28 ± 4.78. The average joint pain (knee) score (VAS) reduced significantly from 40.28 ± 4.78 to 34.77 after 7th day treatment with Arthohills Capsule. The average pain score further reduced significantly from baseline to 28.44 ± 3.45 and 23.78 ± 2.014 on days 14th and 21st respectively [as shown in Fig. No. 1].

The average total WOMAC score at the baseline visit was 48.21 ± 1.123 to 27.12 ± 2.142 was reduced statistically significantly. The average pain sub score in WOMAC was reduced significantly from 10.22 ± 0.452 to 4.11 ± 0.162. The average stiffness sub score in WOMAC was reduced statistically significantly from 3.05 ± 0.03 to 1.03 ± 0.121. The average Physical functioning sub score in WOMAC from 34.11 ± 1.281 to 21.67 ± 1.378 was reduced statistically significantly [as shown in Fig. No. 2].

4. DISCUSSION

Primary objective of study was to evaluate the safety evaluation and tolerability of Arthohills capsule on total clinical fitness, hematological and X-ray parameters in osteoarthritis subjects by assessing change in WOMAC total Score and by using VAS for pain. The subjects were selected accordingly to assessment criteria. For the safety evaluation of Arthohills capsule, the total clinical fitness, hematological and X-ray parameters in osteoarthritis subjects assessed on VAS (Visual analogue scale) and WOMAC Osteoarthritis Index (Western Ontario and McMaster Universities).

Results of this study showed that 33.14% subjects were in 50-60 years of age group. Statistically significant (p<0.001) results are seen in the study. Average VAS pain score of knee joint was assessed on each follow-up shows that decreased trends. WOMAC Osteoarthritis Index sub scales were decreased significantly. Findings show that Arthohill Capsule an Ayurvedic proprietary drug had a significant result in joint pain, stiffness and also improved the physical functions on weight bearing activities.

Composition of Arthohills Capsule is collectively having Vata and Kapha shamaka properties, Dipana, Aamapachana, Rasayana, Vedanasthapana and Shothahar properties. It relieves pain associated with vitiated Vata due to having Ushna Virya and Vatanulomana properties. Maharasnadhi kwatha\(^{(18)}\) and Dasmooladi kwatha\(^{(19)}\) are a polyherbal formulation from Sharangdhar Samhita has the potential for

![Figure No. 1. The average pain in knee joint of subjects assessed by Visual Analogue Scale.](image-url)
providing relief to arthritis patients and Vataha-ra, Vedanasthapana properties. The Kapha Shamaka properties of Sunthee (Zinziber Officinalae Linn), Nirgundi (Vitex Negundo), Guggulu (Balsamodendron Mukul) by its Laghu (light -ness), Ushna, Vatashamak, Vedanashamak and Sukshma Strotoshudhikara properties helps to relieve stambha (stiffness) and shotha (inflammation). Laksha (Laccifer Lacca) and Asthishrunkhala (Vitis Quandragularis) are also a potent Vatashamaka properties and benefi-cials for Asthi dhatu (Bones). No any adverse reaction was noted during the study.

5. CONCLUSION

It is concluded that Arthohills capsule was statistically effective in Osteoarthritis subjects in all parameters for taking study. So the effec-tiveness and safety of Arthohills capsule in the management of OA knee subjects 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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