



Evaluate the efficacy of rhumed strong oil in the management of osteoarthritis of “knee joint”

¹Tiwari H.S., ²Barfa Rajendra, ³Mehta Pooja, ⁴Alam Anzar, ⁵Panda B.P., ⁶Verma Jatinder, ⁷Mangal Gopesh

¹Medical Advisor, ²Research Officer, ³Ayurveda Physician and ⁴Quality Control, Multani Pharmaceuticals Ltd. New Delhi, India

⁵Associate Professor (Pharmaceutical Biotech), Department of Pharmacognosy & Phytochemistry School of Pharmaceutical Education & Research Jamia Hamdard, New Delhi

⁶P.G. Scholar and ⁷Associate Professor Panchkarma Dept., National Institute of Ayurveda, Jaipur

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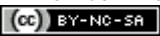
ABSTRACT

The present study entitled as “A Clinical evaluation of rhumed strong oil in the management of osteoarthritis of knee joint. **Material and methods:** Interventional clinical study to evaluate the efficacy of the Rhumed Strong Oil on 50 patients (age group 40-70 years) suffering from osteoarthritis of knee joint. The primary outcome measure will be to assess the efficacy of Rhumed Strong Oil in patients of Joints pain by assessing the degree of pain on day 0, day 15 and day 22. The secondary outcome will be assessing the changes in swelling, tenderness, stiffness and restricted movement in joint. **Result:** Efficacy of Rhumed Strong Oil in the management of Osteoarthritis of knee joint in Degree of pain is analysed between before treatment (BT 0 D) at 0 day and After Treatment (AT 15D) at 15 days. Degree of pain is found to be significantly reduced ($p < 0.05$) at 15th day of treatment ($t=19.73$). Further there is non-significant difference in the Degree of pain between After Treatment (AT 15D) at 15 day and at follow up day (AF 22D) at 22day. **Conclusion:** The efficacy of Rhumed Strong Oil can be due to the synergistic actions of the potent herbs present in the formulation.

Key Words: Rhumed Strong Oil, Knee Joint, Joint pain, Osteoarthritis

Address for Correspondence: Dr. Rajendra Barfa, Research Officer, Multani Pharmaceuticals Ltd, T-10, Okhla Phase II Road, Pocket W, Okhla Phase II, Okhla Industrial Area, New Delhi, Delhi 110020; Email: multaniayurveda@hotmail.com

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INTRODUCTION

Ayurveda aims at physical, social, and spiritual well-being of an individual. The modalities of preventive and curative healthcare have been well expounded in this science and may offer comprehensive solutions for the multifactorial diseases of the humanity. Osteoarthritis (OA) is one such disease wherein a rise in incidence is being observed owing to faulty diet and lifestyle. The disease usually affects in the fourth decade, and the occurrence increases linearly with age.¹ Unilateral OA is more prevalent in male and bilateral OA in female.² It is a degenerative disease characterized by loss of articular cartilage and synovial inflammation, joint stiffness, swelling, pain, and loss of mobility being its hallmark symptoms.³ The disease has a propensity to affect the weight-bearing joints such as the knee and hip most commonly and is hence a potent cause of disability.⁴ The symptoms of OA correlate with *Sandhigata Vata*. *Sandhigata Vata* is explained under *Vatavyadhi*. *Sandhivata* is first described by Acharya Charaka as *Sandhigata Anila* with symptoms of *Shotha* (swelling) which on palpation feels like a bag filled with air and *Shula* (pain) on *Prasarana* (extension) and *Akunchana* (flexion).⁵ Acharya Sushruta also mentioned *Shula* and *Shotha* in this disease leading to the diminution (*Hanti*) of the movement at joint involved.⁶ Madhavakara adds *Atopa* (crepitus in joint)⁷ as additional feature of it. The pathologic of this disease are attributing to the affecting the *Asthi* (bone), *Sandhi* (joint), *Mamsa* (muscle) and *Snayu* (ligament).

In Ayurveda management of OA includes a judicious combination of external therapies (*Bahya Chikitsa*) and internal medication (*Abhyantara Chikitsa*). The *Bahya Chikitsa* include *Janu Basti*, *Abhyanga* (massage), *Jalaukavacharana* (application of leech), *Agnikarma* (cautery), *Basti* (medicated enema), etc. *Abhyantara Chikitsa* include the internal medications in the form of *Churna* (powder of a single herb/combination of herbs), *Kashaya* (decoction), *Vati* (pills), etc. Present trial is an open labeled, single armed, single centric, prospective, interventional clinical study to evaluate the efficacy of the Rhumed Strong Oil on 50 patients of either sex (age group 40-70 years) suffering from osteoarthritis of knee joint. It will be advised to subjects to apply the oil (*Abhyanga*) 2 times a day on the affected knee joint/s for 15 days. The primary outcome measure was to assess the efficacy of Rhumed Strong Oil in patients of Joints pain by assessing the degree of pain on day 0, day 15 and day 22. The secondary outcome will be assess the changes in swelling, tenderness, stiffness and restricted movement in joint (Assessment of

pain will be done by Visual Analogue Scale). No other medication intended for same use as study medication was allowed for these subjects.

MATERIALS AND METHODS

The subjects were enrolled, and informed consent was taken. The subjects were instructed regarding the study procedure and were advised to apply Rhumed Strong Oil on affected joint/joints for 10 minutes in morning and evening for 15 days.

Inclusion Criteria

- Age: from 40-70 years of either sex.
- Subjects with symptoms of Osteoarthritis of knee joint.
- Subjects who are willing to give informed consent any ready to comply the protocol.
- Subjects who are ready to provide regular follow up till the completion of the study.

Exclusion Criteria

- Patients of age below 40 years and above 70 years of either sex.
- Patients having associated Pulmonary Tuberculosis, Burns, Open wounds and infective conditions, allergy, skin sensitivity, Knee joint replacement, Gouty arthritis, Rheumatoid arthritis etc.

Test Product

- Rhumed Strong Oil.

Table No. 01 Content of Rhumed Strong Oil

S.N.	INGREDIENTS	QTY.
1.	<i>Tila Taila</i> (Sesame oil)	130 g
2.	<i>Mahanarayan Taila</i>	40 g
3.	<i>Gandhpoora Taila</i>	15 g
4.	<i>Pudina Satva</i> (Menthol)	5 g
5.	<i>Hyoscyamus niger</i>	10 g
6.	<i>Dhatura metel</i>	10 g
7.	<i>Ricinus communis</i>	20 g
8.	Clove oil	7 g
9.	Nutmeg oil	7 g

Test Product Dosage

Rhumed Strong Oil (prepared by Multani Pharmaceuticals Ltd.)

- Oil applied for 10 minutes to the affected joint/s twice day for 15 days.
- Dose: 10-15 ml for external use.
- Dosage form: Oil

Study Design and Procedure

It is an open labeled, single armed, single centric, prospective, interventional clinical study to evaluate the efficacy of the Rhumed Strong Oil on

50 patients (age group 40-70 years) suffering from osteoarthritis of knee joint. The study was conducted in Panchakarma department, NIA, Jaipur, Rajasthan. It will be advised to subjects to apply the oil 2 times a day on the affected knee joint/s for 15 days. The primary outcome measure will be to assess the efficacy of Rhumed Strong Oil in patients of Joints pain by assessing the degree of pain on day 0, day 15 and day 22. The secondary outcome will be assess the changes in swelling, tenderness, stiffness and restricted movement in joint (Assessment of pain will be done by Visual Analogue Scale). Adverse effects if any were noted down. The subjects were free to withdraw from study if they so desired. No other medication intended for same use as study medication was allowed for these subjects.

Selection of study population

It is an open labeled, single armed, single center, prospective, interventional clinical study to evaluate the efficacy of the Rhumed strong oil on 50 patients between age group 40-70 years suffering from osteoarthritis of knee joint.

Statistics Report

Statistical Analysis of Bio efficacy effect of Rhumed Strong Oil in the management of Osteoarthritis of knee joint. Data are presented as mean \pm SD and were compared using the paired student's *t* test between before treatment & after treatment and one-way ANOVA with "Bonferroni's Multiple Comparison Test" post-test with 95% CI. A *P* value of < 0.05 was considered significant. Data Comparison were made from Day 0 (Before Treatment; BT) to Day 15 (After Treatment; AT) and between Day 0 (Before Treatment) & Day 22 (After Follow up; AF) Data were analysed using Prism 5.0 software (GraphPad, San Diego, CA).

Study Objectives

Primary Objectives:

- To evaluate the changes in joint pain.

Secondary Objectives:

- Assessment of changes in the degree of swelling, stiffness, restricted movement of the joints, tenderness and development of any adverse effect.

Assessment of Subjective parameters

The clinical parameters were assessed at Day 0, day 15 and on day 22. All the subjects completed the trial. The clinical assessment is recorded for the all 50 subjects.

1. Primary End-Point Assessment:

Measures were assessed for degree of pain on day 0, day 15 and day 22.

2. Secondary End Points Assessments:

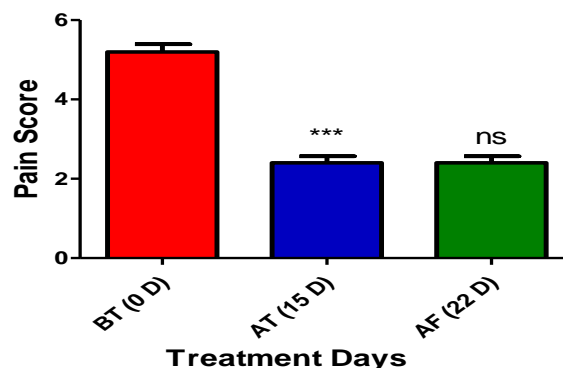
Degree of swelling, stiffness, restricted movement of the joints, tenderness

OBSERVATION AND RESULT

1. Primary End-Point Assessment:

- ##### A. Degree of Pain: Score 9 - Highest; Score 1 - lowest

Graph -01 Degree of Pain score

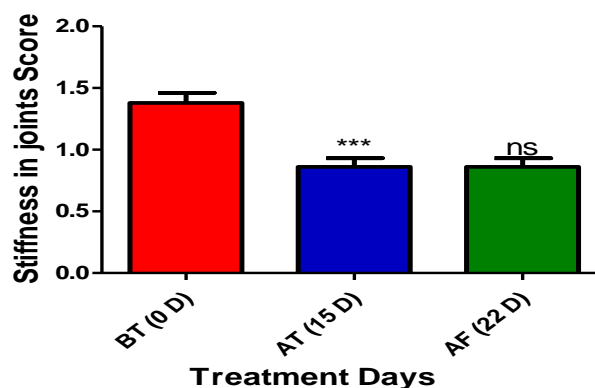


Efficacy of Rhumed Strong Oil in the management of Osteoarthritis of knee joint in Degree of pain is analysed between before treatment (BT 0 D) at 0 day and After Treatment (AT 15D) at 15 day. Degree of pain is found to be significantly reduced ($p < 0.05$) at 15th day of treatment ($t=19.73$). Further there is non-significant difference in the Degree of pain between After Treatment (AT 15D) at 15 day and at follow up day (AF 22D) at 22day.

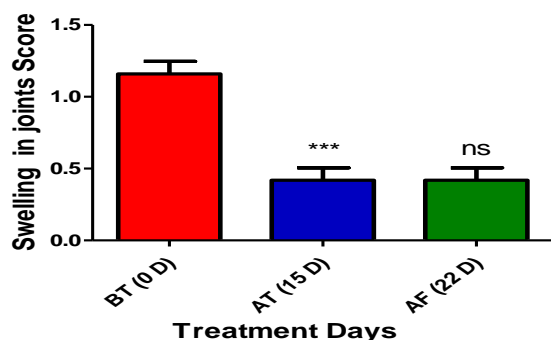
2. Secondary End Point Analysis

A. Stiffness in Joints

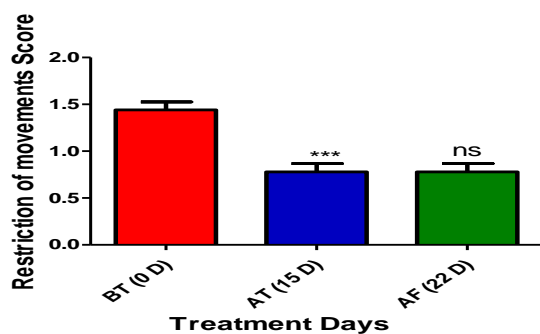
Graph -02 Stiffness in Joints score



Efficacy of Rhumed Strong Oil in the management of Osteoarthritis of knee joint in Stiffness in joints is analysed between before treatment (BT 0 D) at 0 day and After Treatment (AT 15D) at 15 day. Stiffness in joints is found to be significantly reduced ($p < 0.05$) at 15th day of treatment ($t=8.923$). Further there is non-significant difference in the Stiffness in joints between After Treatment (AT 15D) at 15 day and at follow up day (AF 22D) at 22day.

B. Swelling of Joints**Graph -03 Swelling of Joints score**

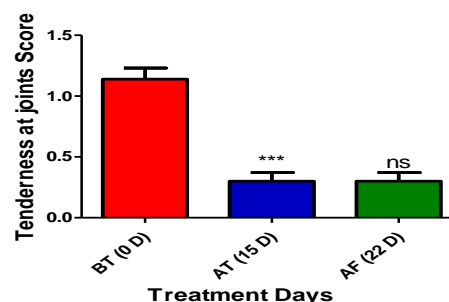
Efficacy of Rhumed Strong Oil in the management of Osteoarthritis of knee joint in Swelling of joints is analysed between before treatment (BT 0 D) at 0 day and After Treatment (AT 15D) at 15 day. Swelling of joints is found to be significantly reduced ($p < 0.05$) at 15th day of treatment ($t=13.16$). Further there is non-significant difference in the Swelling of joints between After Treatment (AT 15D) at 15 day and at follow up day (AF 22D) at 22day.

C. Restriction of Movements**Graph -04 Restriction of Movements score**

Efficacy of Rhumed Strong Oil in the management of Osteoarthritis of knee joint in the Restriction of Movements is analysed between before treatment (BT 0 D) at 0 day and After Treatment (AT 15D) at 15 day. Restriction of Movements is found to be significantly reduced ($p < 0.05$) at 15th day of treatment ($t=9.642$). Further there is non-significant difference in the Restriction of Movements between After Treatment (AT 15D) at 15 day and at follow up day (AF 22D) at 22day.

D. Tenderness at joints

Efficacy of Rhumed Strong Oil in the management of Osteoarthritis of knee joint in the Tenderness at joints is analysed between before treatment (BT 0 D) at 0 day and After Treatment (AT 15D) at 15 day. Tenderness at joints is found to be

**Graph -05 Tenderness at joints score**

significantly reduced ($p < 0.05$) at 15th day of treatment ($t=15.55$). Further there is non-significant difference in the Tenderness at joints between After Treatment (AT 15D) at 15 day and at follow up day (AF 22D) at 22day.

DISCUSSION

Rhumed strong oil has been prepared from a polyherbal Ayurvedic formulation which contains herbs that have been proved effective in the management of osteoarthritis of knee joints(s).

Tila Taila It is extracted from the seeds of *Sesamum indicum*. Sesame oil contains a crystalline substance sesamin and phenol compound sesamol. Sesame oil is used as a base for oil preparation. *Tila Taila* is *Madhura Ras* and *Vipaka*, *Balya* and *Rasayana* in *Karma*; it nourishes and strengthens all *Dhatu*, checks *Dhatukshaya* and thus alleviates *Vata*. *Snigdha* and *Guru Guna* decreases *Rukshata* of *Vata* and with the help of *Ushna Guna* and *Veerya* it alleviates *Vata*. *Tila Taila* is *Brimhana/ Lekhana*, *Prinana*, *Vrushya*, *Tvakprasadana*, *Mardavakara*, *Sthairyakara*, *Balya*, *Garbhashaya* *Shodhaka*, *Bhagna sandhanakara*, *Medhavardhaka*, *Keshya*, *Shulaprashamana*, *Ropaka*, *Vrana-Nashaka*. It also possesses anti-inflammatory and anti-oxidant properties. It is good source of Vitamin E (1.4mg/100g) (Sesame oil, Wikipedia, the free encyclopedia.com) and it also contains magnesium, copper, calcium, iron, zinc and Vitamin B₆.

Mahanarayan taila is a well-known *Vata* balancing herbal oil formula used in Ayurvedic medicine for centuries. It is a rich combination of antiarthritic Ayurvedic herbs, produce no irritation on skin and arrest further progress of chronic arthritic changes of joints, pain, stiffness, restricted movement, distortion and restores normal joint function. *Gandhpoora Taila*: Essential oils of *Gandhapoora taila* (*Gaultheria fragrantissima*) possess antimicrobial, anti-inflammatory, and analgesic properties.

Pudina Satva is the natural laevo-rotatory menthol obtained from various species of *Mentha* (Fam. Lamiaceae). *Mentha arvensis* is the primary species of mint used to make natural menthol crystals and natural menthol flakes. It is a colourless, hexagonal crystals, usually needle-like, or in fused masses or crystalline powder; odour, pleasant and peppermint-like; taste, warm and aromatic followed by a cool sensation. Menthol is extracted from Bark and Leaves of trees of various *Mentha* species. It can be prepared synthetically as well. It exhibits local anaesthetic and counterirritant properties. It imparts a cooling sensation over the area of contact. It also relieves musculoskeletal pain and inflammation.

Hyoscyamus niger is used in traditional herbal medicine for ailments of the bones, rheumatism, toothache, asthma, cough, nervous diseases, and stomach pain. It might also be used as analgesic, sedative, and narcotic in some cultures. Adhesive bandages with henbane extract behind the ear are reported to prevent discomfort in travel-sick people. Henbane oil is used for medicinal massage. The seeds of *Datura* are analgesic, anthelmintic and anti-inflammatory and as such, they are used in the treatment of stomach and intestinal pain that results from worm infestation, toothache, and fever from inflammation. The juice of its fruit is applied to the scalp, to treat dandruff and falling hair.

Ricinus communis have been widely used in traditional medicine such as abdominal disorders, arthritis, backache, muscle aches, bilharziasis, chronic backache and sciatica, chronic headache, constipation, expulsion of placenta, gallbladder pain, period pain, menstrual cramps, rheumatism, sleeplessness, and insomnia.

Clove oil has traditionally been used for a variety of purposes, including: as an antimicrobial, to help kill bacteria, as a pain reliever for conditions such

as toothache and muscle pain, for digestive upset, and to relieve respiratory conditions like cough and asthma.

Nutmeg essential oil relieves joint pain, elevates mood, regulates menstrual cycles, hormones in women and treat the common cold, lung problems, but it also has several fortifying compounds that supply crystal clear skin and healthy hair. This, coupled with its revitalizing scent, makes it a popular addition to perfumes, soaps, shower gels, cleansers, moisturizers, as well as shampoos, conditioners and oral, dental care products.

CONCLUSION

In the present project subjects applied Rhumed Strong Oil which shows improvements in joint pain and changes in swelling, tenderness, stiffness and restricted movement in joint. From the statistical analysis of the clinical data for the treatment of in the management of Osteoarthritis of knee joint by Rhumed Strong Oil of Multani Pharmaceuticals Ltd. is found to be controlling pain in 50 subjects after 15 days of treatment and in 22 day. Further there is non-significant difference in the pain at follow up day when compared to end of the treatment day. The Secondary End Points Assessments scores like Degree of swelling, stiffness, restricted movement of the joints and tenderness are also significantly reduced or became nil after the treatment period. In general, Rhumed Strong Oil is found to be effective in pain in the patients suffering from osteoarthritis of knee joint(s). And there is no change in these factors at follow up day (at 22 day) when compared to end of the treatment day. The efficacy of Rhumed Strong Oil can be due to the synergistic actions of the potent herbs present in the formulation. There were no adverse effects either reported or observed during the clinical study.

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