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# To evaluate safety and efficacy of Arthrohills oil in subjects with Musculoskeletal Pain

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## ABSTRACT

Musculoskeletal pain affects bones, joints, ligaments, tendons or muscles. An injury such as a fracture may cause sudden, severe pain. According to the World Health Organization (WHO), 20-33% of the world's population has some form of chronic musculoskeletal pain, translating to 1.75 billion people globally. Outdoor patients, having chronic pain of musculoskeletal origin were advised Arthrohills oil external application locally as few drops for small joints and up to 2-3 ml for the larger joints once in a day for external application with gentle massage for 15 min up to 6 weeks were used in this study. Assessment points were Pain, Tenderness, Swelling and Joint motility. We can conclude that, effect observed in all parameters is significant. Arthrohills oil was safe and effective in musculoskeletal pain.

**Key words:** Musculoskeletal pain, Arthrohills oil external application.

## INTRODUCTION

Health is the situation of a living thing when its vital functions are functioning properly and harmoniously, contributing to its preservation and to the normal growth of its inhabitants.<sup>[1]</sup>

Musculoskeletal pain affects bones, joints, ligaments, tendons or muscles. An injury such as a fracture may cause sudden, severe pain.

Musculoskeletal pain can be acute, meaning it is sudden and severe. Or the pain can be chronic (long-lasting). You may have localized pain (in one area of your body), or it may affect your entire body. Chronic musculoskeletal pain (in particular, low back pain) is

the main contributor to disability worldwide.<sup>[2]</sup> According to the World Health Organization (WHO), 20 to 33% of the world's population has some form of chronic musculoskeletal pain, translating to 1.75 billion people globally.<sup>[3]</sup> The most prevalent forms of musculoskeletal pain are chronic low back pain, neck pain, and the pain associated with osteoarthritis and rheumatoid arthritis, but musculoskeletal pain also includes sprained muscles, pain associated with fracture, shoulder pain, and others. Advancing age increases the risk of musculoskeletal pain, although it may occur at any age. Chronic musculoskeletal pain is mainly a consequence of a complex reciprocation of biochemical, mechanical, psychological, and social components.<sup>[4]</sup> The patterns of musculoskeletal pain problems vary greatly by age and sex, e.g., knee pain from osteoarthritis is extremely common in the elderly, affecting over one-third of people over age 60, while the prevalence of pain is about 1.5 to 2 times more common in women than in men, and the ratio is over four females to one male for fibromyalgia.<sup>[5]</sup>

Common causes of musculoskeletal pain include:

- Bone fractures
- Joint dislocation (when something forces a joint out of its proper position).

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- Direct blows to muscles, bones or joints.
- Overuse injuries
- Poor posture
- Sprains

#### What are the symptoms of musculoskeletal pain?

Your symptoms may vary depending on the cause of your musculoskeletal pain. Common symptoms include:

- Aching and stiffness.
- Burning sensations in the muscles.
- Fatigue.
- Muscle twitches.
- Pain that worsens with movement.
- Sleep disturbances.

## MATERIALS AND METHODS

### Inclusion criteria

1. Outdoor patients, having chronic pain of musculoskeletal origin (e.g., low backache, knee, shoulder, elbow, wrist, ankle, and neck pain for more than 12 weeks).
2. Patients of either sex aged between 25 and 65 years.

### Exclusion criteria

1. History of any trauma/fractured joint/surgical/diagnostic intervention with reference to the affected joint(s)
2. Gross disability in performing daily normal routine, i.e., bed-ridden patients or confined to a wheelchair
3. Patients with co-morbidities such as gouty arthritis, rheumatoid arthritis, and psoriatic arthritis
4. Patients having any deformity of knee hip or back altering their gait and posture
5. Patients with uncontrolled hypertension (>160/100 mm of Hg)

6. Patients with uncontrolled diabetes mellitus (HbA1c >9%)
7. Patients with evidence of malignancy
8. Patients on prolonged (>6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc., or any other drugs that may have an influence on the outcome of the study
9. Patients who have a history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke, or severe arrhythmia in the last 6 months
10. Patients with any severe renal or hepatic or any other disorder which may interfere in the study
11. Pregnant/lactating woman.
12. Patients who are currently participating in any other clinical trial
13. Any other condition which the Principal Investigator thinks may jeopardize the study

### Trial intervention

Arthrohills oil external application advised to apply locally as few drops for small joints and up to 2–3 ml for the larger joints once in a day for external application with gentle massage for 15 min up to 6 weeks were used in this study.

First visit (on 1st week), second visit (on 2nd week), third visit (on 3rd week), fourth visit (on 4th week), and last visit (on 6th week)

Final follow up after 6 weeks regarding safety and efficacy

### Assessment points

Pain, Tenderness, Swelling and Joint motility

The patients were examined weekly, and suitable scoring pattern and objective signs were recorded to assess any change present in the patients. The initial findings were considered as baseline score, and subsequent scores at first visit (on 1<sup>st</sup> week), second visit (on 2<sup>nd</sup> week), third visit (on 3<sup>rd</sup> week), fourth visit (on 4<sup>th</sup> week), and last visit (on 6<sup>th</sup> week) were recorded. After completion of 6 weeks of the

treatment, the efficacy of the therapy was assessed on the basis of the subjective criteria as stated below.

A validated modified version of the WOMAC questionnaire suitable for Indian patients and available in several Indian languages was used. Patients provided categorical answers for scoring (none = 0, mild = 1, moderate = 2, severe = 3, extreme = 4)

For nature of swelling assessment was carried out as follows

Joint swelling to a maximity abnormal degree= 4, markedly abnormal swelling=3, joint swelling obvious even on casual observation=2, joint swelling which may not be apparent on casual inspection, but should be recognizable to experienced examine=1, no swelling=0.

### Oil ingredients

Arthrohills oil / Ayurvedic proprietary medicine (for external use only)

Each 100 ml oil contains – (BPN- Bhavprakash Nighantu)

SN	Contents	Latin name	Reference
1.	Nirgundi oil	<i>Vitex negundo</i>	BPN pg. No. 329 (20 ml)
2.	Nilgiri oil	<i>Eucalyptus globulus</i>	BPN pg. No. 804 (6.6ml)
3.	Dhaturo oil	<i>Datura stramonium</i>	BPN pg. No. 304 (5ml)
4.	Erand oil	<i>Ricinus communis</i>	BPN pg. No. 286 (5.5 ml)
5.	Lemon grass oil	<i>Cymbopogon citratus</i>	BPN pg. No.370 (5 ml)
6.	Kalonji oil	<i>Nigella sativa</i>	BPN pg. No. 32 (5 ml)
7.	Proprietary blend	<i>Syzygium aromaticum</i> , <i>Cinnamomum zeylanicum</i> , <i>Myristica fragrans</i> , <i>Cinnamomum</i>	BPN pg. No. 209, 216, 206, 218, 25, 639 (5ml)

		<i>tamala</i> , <i>Trachyspermum ammi</i> , <i>Sesamum indicum</i>	
8.	Kapur oil	<i>Cinnamomum camphora</i>	BPN pg. No. 168 (10ml)
9.	Gandhapura Tail	<i>Gaultheria fragrantissima</i>	BPN pg. No. 809 (28 ml)
10.	Gandhabiroja tail	<i>Pinus longifolia</i> (sap)	BPN pg.no. 189 (5 ml)
11.	Til oil	<i>Sesamum indicum</i>	BPN pg. No. 639 (4.9 ml)

### RESULTS AND DISCUSSION

The key objective of this study was to evaluate the efficacy of Arthrohills oil external application in the management of musculoskeletal pain.

**Table 1: Age wise distribution**

Age Group	Frequency	Percentage
20-30 Years	11	22.92%
31-40 Years	20	41.67%
41-50 Years	11	22.92%
51-60 Years	5	10.42%
> 60 Years	1	2.08%
Total	48	100.00%

**Table 2: Gender wise distribution**

Gender	Frequency	Percentage
Male	26	54.17%
Female	22	45.83%
Total	48	100.00%

**Table 3: Occupation wise distribution**

Occupation	Frequency	Percentage
Housewife	1	2.08%
Service	31	64.58%
Student	15	31.25%

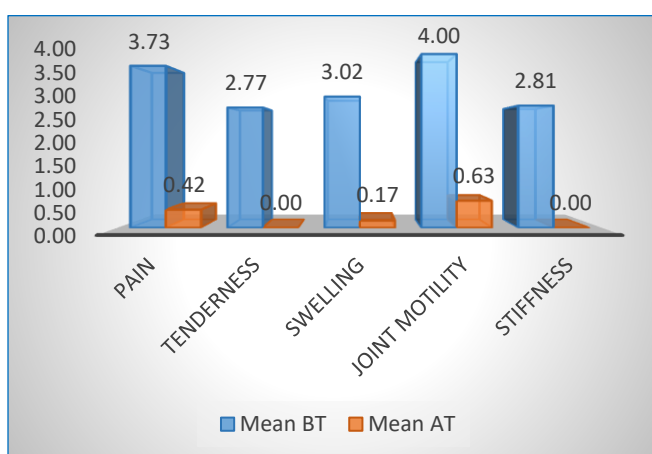
Retired	1	2.08%
Total	45	93.75%

**Table 4: Effect on subjective parameters**

Parameters	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	B T	A T	B T	A T	B T	A T				
Pain	3.73	0.42	4.00	0.00	0.49	0.69	-6.308 <sup>b</sup>	0.000028	88.83	Sig
Tenderness	2.77	0.00	3.00	0.00	0.85	0.50	-6.135 <sup>b</sup>	0.000085	100.00	Sig
Swelling	3.02	0.17	3.00	0.00	0.66	0.66	-6.402 <sup>b</sup>	0.000015	94.48	Sig
Joint motility	4.00	0.63	4.00	1.00	0.58	0.58	-6.207 <sup>b</sup>	0.000054	84.38	Sig
Stiffness	2.81	0.00	3.00	0.00	0.57	0.57	-6.127 <sup>b</sup>	0.000090	100.00	Sig

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table, we can observe that, P-Value for all parameters is less than 0.05. Hence, we can conclude that, effect observed in all parameters is significant.

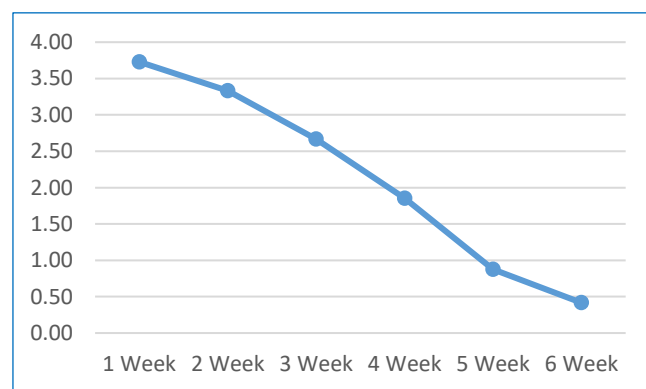
**Fig 1: Efficacy Post Treatment**



**Table 5: Pain assessment during follow-ups.**

Pain	Mean	SD	% Change
1 week	3.73	0.49	-
2 weeks	3.33	0.69	10.61
3 weeks	2.67	0.66	28.49
4 weeks	1.85	0.58	50.28
5 weeks	0.88	0.57	76.54
6 weeks	0.42	0.50	88.83

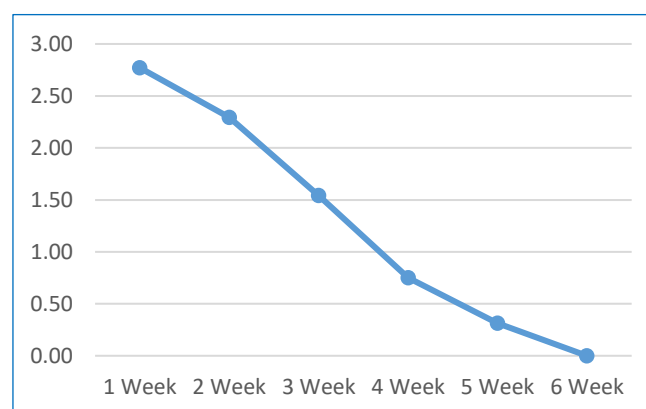
**Fig 2: Follow Up wise improvement in Pain**



**Table 6: Tenderness assessment during follow-ups.**

Tenderness	Mean	SD	% Change
1 week	2.77	0.81	-
2 weeks	2.29	0.85	17.29
3 weeks	1.54	0.50	44.36
4 weeks	0.75	0.44	72.93
5 weeks	0.31	0.47	88.72
6 weeks	0.00	0.00	100.00

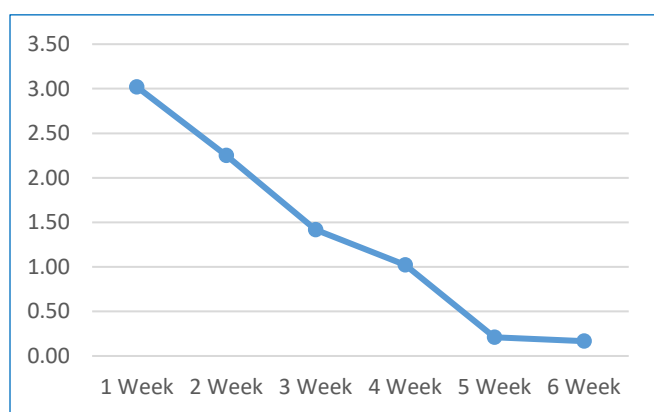
**Fig 3: Follow Up wise improvement in Tenderness**



**Table 7: Swelling assessment during follow-ups.**

Swelling	Mean	SD	% Change
1 week	3.02	0.64	-
2 weeks	2.25	0.53	25.52
3 weeks	1.42	0.82	53.10
4 weeks	1.02	0.56	66.21
5 weeks	0.21	0.41	93.10
6 weeks	0.17	0.38	94.48

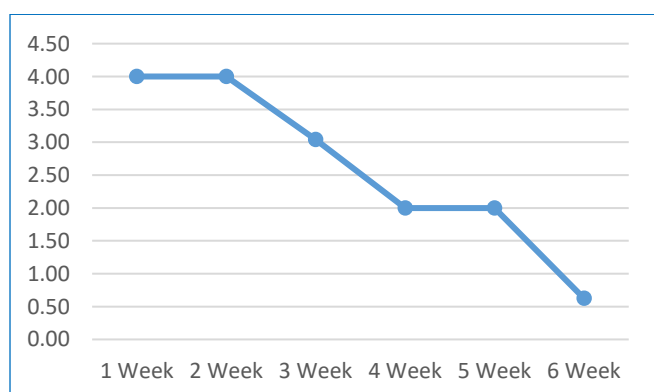
**Fig 4: Follow Up wise improvement in Swelling.**



**Table 8: Joint mobility assessment during follow-ups.**

Joint Mobility	Mean	SD	% Change
1 week	4.00	0.00	-
2 weeks	4.00	0.00	0.00
3 weeks	3.04	0.20	23.96
4 weeks	2.00	0.00	50.00
5 weeks	2.00	0.00	50.00
6 weeks	0.63	0.57	84.38

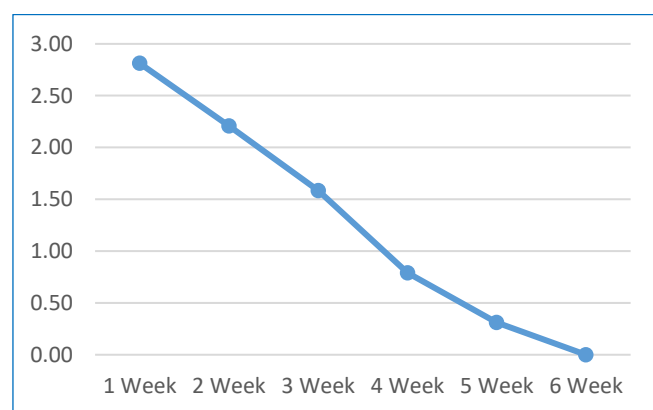
**Fig 5: Follow Up wise improvement in Joint Mobility**



**Table 9: Stiffness assessment during follow-ups.**

Stiffness	Mean	SD	% Change
1 week	2.81	0.79	-
2 weeks	2.21	0.77	21.48
3 weeks	1.58	0.54	43.70
4 weeks	0.79	0.46	71.85
5 weeks	0.31	0.47	88.89
6 weeks	0.00	0.00	100.00

**Fig 6: Follow Up wise improvement in Stiffness**



Composition of Arthohills oil is collectively having properties of reduction of pain, reduction of inflammation properties.

### CONCLUSION

Arthohills oil was safe and effective in musculoskeletal pain.

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