

# Clinical Evaluation of Unani Formulation in the Management of “*Wajaul Mufasil* (Osteo-Arthritis)”- A Randomized, Single Blind Clinical Trial

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**Abstract:** *Wajaul Mufasil* (Osteo-arthritis = joint pain with inflammation) especially for knee Joint. Arthritis is very common; it is an inflammation of the joint. It can affect one joint or multiple joints. It's a chronic progressive degenerative joint disease affecting mainly the articular cartilage of the big weight bearing joints of the body. There are more than 100 different types of arthritis, with different causes and treatment methods. The first known traces of human arthritis date back as far as 4500 BC. It is seen in Italy and Austria. Around 30-50% of the world's population experiences OA for knee joint pain at some time in their lives though; the pain is short lived and responds to symptomatic measures. Unani formulation as Ajwain (*Trachyspermum ammi*), Haloon (*Lepidium sativum*), Kalonji (*Nigella sativa*) and Methi (*Trigonella foenum graecum*) is one of the oldest treatments of Unani practiced by Unani physician. It is used generally as a powder form with oral administration. This formulation effect as analgesic, anti-inflammatory, antimicrobials and immuno-modulator, Interventions were given in a total of 60 patients for 30 days. Was administered Unani formulation only. The objective of the study is to evaluate the efficacy of Unani formulation in the management of *Wajaul Mufasil*. The result indicated clinically significant.

**Keywords:** *Wajaul Mufasil*, Unani formulation, Paracetamol, VAS

## 1. Introduction

*Wajaul Mufasil* (Osteoarthritis for knee joint Arthritis is very common; it is an inflammation of the joint. It can affect one joint or multiple joints. It's a chronic progressive degenerative joint disease affecting mainly the articular cartilage of the big weight bearing joints of the body. There are more than 100 different types of arthritis, with different causes and treatment methods. The first known traces of human arthritis date back as far as 4500 BC. It is seen in Italy and Austria. Around 30-50% of the world's population experiences OA for knee joint pain at some time in their lives though; the pain is short lived and responds to symptomatic measures. It becomes a major social and health problem with frequent cause of activities limitation in people specifically among individuals less than 45 years of age. It is the 5<sup>th</sup> most frequent reason to visit physician, the 7<sup>th</sup> most cause for hospitalization and 8<sup>th</sup> most cause for surgical procedures.<sup>1</sup>

The world's population experiences knee joint pain and reported its consequences as a loss of more than 30 million days of work each year, approximately 1.4 working days per person per year. 20% of all disabling occupational injuries and 10-15% of all sickness related absence significantly increase in the last 20 years with knee joint pain.<sup>2</sup>

*Wajaul Mufasil* is usually treated with oral or parenteral administration of NSAID's, which causes several side effects. Scholars of Unani medicine used Unani formulations and various regimens for the successful treatment of OA for knee joint. To evaluate the efficacy of a Unani formulation

as well as modern drugs paracetamol this study was conducted.<sup>3</sup>

## 2. Material and Methods

This study was carried out in 60 adult patients who were attending the OPD and IPD of State Takmeel Ut-tib College & Hospital, Lucknow. These patients entered into the trial only after signing the informed written consent and sittings 0, 7, 15, 21 and 30 for 30 days.

**Study design:** A randomized, Single blind, Stander-controlled clinical study.

**Subjective parameters:** Knee joint pain, tenderness and difficulty in movements

**Inclusion Criteria:** Clinically and radiologically diagnosed patients, either sex, Patient in age group of 40-80 years, only osteoarthritis due to degenerative, and agreed to sign the informed consent and follow the protocol.

**Exclusion Criteria:** Age less than 40 years and more than 80 years, Pregnancy and lactation, Systemic illness such as Liver, Kidney, Cardiac disorders Diabetes mellitus, Hypertension, OA due to trauma & infections, Osteomyelitis, Tuberculosis, Overweight.

**Intervention:** Time of medication 6gm bid with water about 30 day

**Unani formulation used in trial:**

- Ajwain (*Trachyspermum ammi*) 1.5 mg

- Haloon (*Lepidium sativum*) 1.5 mg
- Kalonji (*Nigella sativa*) 1.5 mg
- Methi (*Trigonella foenum graecum*) 1.5 mg, Dosage 6 gm BID about 30 days.

**Stander- control:** Tablet Paracip (Paracetamol) - 500 mg BID (Cipla)

**Efficacy assessments:** Efficacy was assessed by the VAS, Five point scales, which were administered at base line 0, 7, 15, 21, and 30 days. Safety was assessed by clinically and radiological examinations. Adverse events were recorded at every visit after the base line visit.

**Statistical analysis:** Quantitative analysis of the data was expressed as median with range and differences between two groups were compared by *Kruskall Wallis (Non parametric ANOVA)* test. Chi square test was used to study the significance of efficacy of drugs.

**Ethics:** The study was performed in accordance with good clinical practices.

**Table 1:** Demographic data of patients on entry

Parameters	Unani formulation 30 patients	Stan. Cont. 30 patients
Age (years) Mean	40 ± 80	46 ± 74
Weight (Kg) Mean	88 ± 66	90 ± 60
Sex ratio (M:F)	2:2	2:2
Mizaj (D/B/Sa/Sf)	8/12/8/2	9/11/9/1
Community (Mu/Hi)	16/14	20/10
dietary habit, (V/Nv)	14/16	12/18
X-ray findings (N/D)	00/30	00/30
Duration of illness	About 3 to 8 years	About 1 to 6 years
<b>Responses</b>		
Excellent	10	10
Good	15	12
Poor	05	06
No response	00	02

**Side effects:** Non occurrence of any toxic or adverse effect during the treatment period.

### 3. Result & Discussion

The study was conducted to evaluate the efficacy of Unani formulation in *Wajaul Mufasil*. The discussion regarding demographic data, clinical symptoms and objective and subjective parameters findings are as follows. In this study a maximum of 15 (50%) of the patients were found to be between the age of 41- 80 years recorded, which coincides with API's description as the highest prevalence of LBP is in persons aged between 45- 90 years.<sup>5,6</sup>

This study reveals that the prevalence of the disease is more in male, as because out of 60 patients 30 (50%) were found to be male only, which is highly contrary to the description of Harrison's principles of internal medicine, but this may be due to the equals enrollment of the male and females patients.<sup>4,7</sup>

Out of 20 patients both in test and control group, 36 (60%) belongs to Muslim community and 24 (40%) Hindu community. This is may be due to the high number of patients attending S.T.T.C. & H., Lucknow hospital.

A maximum of 33 (55%) of *Balghami Mizaj* patients were found in this study followed by 10 (16.66%) *Damavi* and 14 (23.33%) *Safravi* and 03 (5.00%) *Saudavi Mizaj*. This finding is in accordance to the description given by Ibn Sina, Ahmed bin Mohammed Tabri that disease is more frequent in people with *Balghami Mizaj*.<sup>8,9</sup>

This study reported that the high incidence of *Wajaul Mufasil* with 33 (55%) was found in medium community, followed by 12 (20%) poor community, 9 (15%) and 6 (10%) high community. This resembles the incidence rate mentioned by Harrison principles of internal medicine as 50% of medium community adults were the victims of the disease.<sup>10,11</sup>

Out of 20 patients of *Wajaul Mufasil*, 29 (48.33%) had high body weight that is between 61-70 kgs, followed by 20 (33.33%) between 51-60 kgs, 12 (20%) between 71-80 kgs 6 (10%) between 41-50 kgs and 3 (5%) were between 81-90 kgs. This is may be due to the high number of patients attending NIUM hospital.

This study gives us the information that 25 (41.67%) patients reported to be having < 6 months of illness. Followed by 11 (18.33%) with 1-2 years, 8 (13.33%) with 3-5 years, 6 (10%) with more than 10 years, and 5 (8.33%) with 6-10 years of illness. This is highly coincides with the report as 50% mentioned by Souhani. R. L and J. Moxhan in text book of medicine.<sup>13,14</sup>

X-ray findings in this study evidences that out of 20, 41 (68.33%) patients of *Wajaul Zahar* presented normal study, and 19 (31.67%) with degenerative findings, which inversely reflects the reports mentioned in the text book of medicine described by Souhani. R. L and J. Moxhan as 25% of the case of LBP were found with normal study and 50% with degenerative findings.<sup>3,15</sup>

Before starting the treatment 17 (85%) patients, has pain in moderate grade and 3 (15%) patients, severe pain. After the treatment 12 (60%) patients came down from moderate to mild degree. Only 8 (40%) patients remained in moderate grade.

Before starting the treatment 7 (35%) patients, has tenderness in mild 13 (65%) in moderate tenderness. After the treatment, 1 (5%) patient improved completely, after the treatment 15 (75%) patients came down from moderate to mild degree. Only 4 (20%) patients remained in moderate grade. As shown in the out of total number of patients,

Before starting the treatment 11 (55%) patients, has difficulty of movement in mild 9 (45%) in moderate pain. After the treatment, 16 (80%) patients in mild, 1 (5%) patients in moderate degree. Only 2 (10%) patients in moderate degree. Mean VAS scores before treatment was 4.30, after treatment it was found to be at<sup>13</sup>

This data statistically found significant in *Wajaul Mufasil* at p values < 0.001. A significant improvement (P = < 0.001: *Kruskall – wallis*) was observed in test group when the pre and post values of pain, Tenderness and difficulty of movement.

#### 4. Conclusion

Unani formulation is effective in controlling the signs and symptoms of *Wajaul Mufasil*. This drug is well tolerated and safe.

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