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Clinical validation of a Unani pharmacopoeial formulation - Habb-e-Irq un Nisa in Waja'al-Mafāsil (Rheumatoid Arthritis)

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Abstract
Each participant was well informed about the trial and written consent was obtained before initiation of the study. Demographic data and information on the present disease condition, concomitant disease and therapy was recorded. Thorough general physical and systemic clinical examination was carried out. Signs and Symptoms pertaining to Rheumatoid arthritis were recorded in CRF. The vital parameters like blood pressure, heart rate, temperature and respiratory rate were also recorded. Blood sample were collected for the evaluation of laboratory parameters like, complete blood picture, kidney function test, liver function test and routine, microscopic examination of urine and X-Ray of affected joints were done. All clinical and laboratory follow up were done at every 4 weeks.
The study was carried out in a total number of 130 patients of Rheumatoid arthritis satisfying the criteria, 90 patients completed the trial. All the patients received treatment with Habb-e-irq un Nisa, out of 90 subjects 43 patients got complete remission, 46 patients got partially remission, 01 patients showed poor remission and 01 patients dropped out. No hepatotoxic and nephrotoxic side effects noticed during the course of study. The clinical and laboratory findings after treatment have shown that Habb-e-irq un Nisa possessed efficacy in the treatment of Rheumatoid arthritis.

Keywords: Rheumatoid arthritis, Habb-e-irq un Nisa, unani medicine, remission

Introduction
The term Waja'al-Mafāsil consists of two words, "Waja" means pain and "Mafāsil" means joints, hence Waja'al-Mafāsil means pain in joints. In the classical Unani texts, Waja'al-Mafāsil is broadly explained and its clinical findings closely resemble the findings of rheumatoid arthritis (RA) mentioned in modern system of medicine. Waja'al-Mafāsil is also known as Gathiya (Arzānī, 1931; Majūsī, 2010) [3, 10] and this is one of the hereditary diseases (Ibn Sīnā, 2007) [6]. Buqrāt (Hippocrates), Jālīnūs (Galen), Rāzī (Rhazes), Ibn Sīna (Avicenna) and other Unani physicians described the painful joints of hands and feet under the term Waja'al- Mafāsil. Involvement of other joints like hip, heel, back and toes are called sequentially in the name of Waja'al-Khāsira, Waja'al-'Aqib, Waja'al-Qatan and Niqris (Ibn Sīnā, 2007) [6].
Rāzī (Rhazes) and Ibn Sīna (Avicenna) described the main causative factors of Waja'al-Mafasil (Rheumatoid arthritis) as weakness of joints, impairment of temperament of whole body/single organ, such as joints. Furthermore, they described the reason of Waja'al-Mafasil (Rheumatoid arthritis) as Qillat-i-Harārat Gharīziyya (deficient innate heat), it has also been proved that temperature of the joints is less than other parts of the body, according to the Unani physicians absorption of the morbid humours is slow at less temperature, it is a common reason of accumulation of wastages in the joints. Vigorous exercise or hard physical work associated with improper or poor nutrition is also important reason of Waja'al- Mafasil (Rheumatoid arthritis). Waja'al-Mafasil (Rheumatoid arthritis) is the most common form of chronic inflammatory joint diseases. Besides Sū'-i-Mizāj (derangement of temperament), there are several other concepts defining the disease. According to Ibn Sīna (Avicenna), the causative organism of the disease is Ajsām-i-Khabīsa (foul bodies) while another group says that Hāmiz Labanī (lactic acid) is the root cause which is produced by the derangement of digestive process and accumulates in the blood and joints and produces Waja'al-Mafasil (Rheumatoid arthritis). Depending upon the Mādda affecting the joints,

Balgham (phlegm) predominates, Dam (blood) and Safrā' (bile) are next to it and quite rarely, Sawdā' (black bile) is involved. In some cases more than one Khilt (humour) isinvolved (Rabban, 1992) [13].

According to Shaykh Bū Alī Sīna (Avicenna) the greatest Unani physician of his time, Waja'al-Mafasil (Rheumatoid arthritis) is a clinical condition of pain with or without stiffness in specific joint or more than one joint caused by accumulation of Rutūbat Gharība (foreign humor) in the joints. Waja'al-Mafasil (Rheumatoid arthritis) affects the people inthe age group of 16-35 years. Indigestion, prolonged breast-feeding, poverty, getting wet, cold climate, worry etc are its predisposing factors. Four types of the disease have been described on the basis of the Khilt involved whichare Balghamī, Damwī, Safrāwī and Sawdāwī. In Waja'al-Mafāsil Balghamī, color of the skin over the affected joint is whitish and joint swelling is less. The pain is deep seated and the patients are often obese. Other symptoms of Ghalaba-i-Balgham (phlegm preponderance) are also present.

In Waja'al-Mafāsil Damwī, there is redness of the skin over the affected joint. Joint swelling is visibly marked and the pain is severe. Other symptoms of Ghalaba-i-Dam (blood preponderance) are also present.

In Waja'al-Mafāsil Safrāwī, there is a slight yellow discoloration of the skin over the affected joint. Joint swelling is less than that of Damwī type. Pain and burning sensation along with other symptoms of Ghalaba-i-Safrā (Yellow bile preponderance) are also found.

According to the modern concept, Waja'al-Mafasil (Rheumatoid arthritis) is a chronic inflammatory disease of unknown etiology marked by a symmetric, peripheral polyarthritis. It is the most common form of chronic 1 inflammatory arthritis and often results in joint damage and physical disability. Because it is a systemic disease, RA may result in a variety of extraarticular manifestations, including fatigue, subcutaneous nodules, lung involvement, pericarditis, peripheral neuropathy, vasculitis, and haematologic abnormalities. Cartilage destruction, bone erosions, and joint deformity are hallmarks of RA. The presenting symptoms of RA typically result from inflammation of the joints, tendons, and bursae. Patients often complain of early morning joint stiffness lasting more than 1 hour and easing with physical activity. The earliest involved joints are typically the small joints of the hands and feet. The initial pattern of joint involvement may be mono articular, oligoarticular (≤4 joints), or polyarticular (>5 joints), usually in a symmetric distribution. The wrists, MCP, and PIP joints are the most frequently involved joints. Progressive destruction of the joints and soft tissues may lead to chronic, irreversible deformities. Extra articular manifestations may develop during the clinical course of RA, even prior to the onset of arthritis. Patients most likely to develop extraarticular disease have a history of smoking, early onset of significant physical disability, and test positive for serum RF. Subcutaneous nodules, secondary Sjögren's syndrome, pulmonary nodules, and anaemia are among the most frequently observed extraarticular manifestations. The findings, including rheumatoid nodules or radiographic joint damage occur rarely in early RA. Waja'al-Mafasil (Rheumatoid arthritis) affects approximately 0.5–1.0% of the adult population worldwide. The incidence of RA increases between 25 and 55 years of age after which it plateaus until the age of 75 and then decreases. RA occurs more commonly in females than in males with a ratio of 3:1 (Colledge *et al*, 2010) [4] which shows the possible role of oestrogen in disease pathogenesis. Oestrogen enhances the immune response. Osetrogen can stimulate production of tumor necrosis factor alpha (TNF-α), a major cytokine in the pathogenesis of RA. The propagation of Waja'al-Mafasil (Rheumatoid arthritis) is an immunologically mediated event in which joint injury occurs from synovial hyperplasia; lymphocytic infiltration of synovium; and local production of cytokines and chemokines by activated lymphocytes, macrophages, and fibroblasts. The HLA-DRB1 gene is a major histocompatibility complex (MHC) gene which contributes to RA susceptibility. Cigarette smoking confers a relative risk for developing RA of1.5-3.5.

In approximately two-thirds of patients, it begins insidiously with fatigue, anorexia, generalized weakness, and vague musculoskeletal symptoms until the appearance of synovitis becomes apparent. This prodromal may persist for weeks or months and differential diagnosis. Specific symptoms usually appear gradually as several joints, especially those of the hands, wrists, knees, and feet, become affected in a symmetric fashion. In ~10% of individuals, the onset is more acute, with a rapid development of polyarthritis, often accompanied by constitutional symptoms, including fever, lymphadenopathy, and splenomegaly. In approximately one-third of patients, symptoms may initially be confined to one or a few joints. Although the pattern of joint involvement may remain asymmetric in some patients, a symmetric pattern is more typical. Clinical manifestations include articular and extra-articular manifestations. Articular manifestations include symmetric polyarthritis of peripheral joints with pain, tenderness, and swelling of affected joints; morning stiffness is common; PIP and MCP joints are frequently involved; joint deformities may develop after persistent inflammation. Extra-articular manifestations include Cutaneous– rheumatoid nodules and vasculitis; Pulmonary– nodules, interstitial disease, BOOP, pleural disease and Caplan's syndrome; Ocular–kerato conjunctivitis sicca, episcleritis and scleritis; Hematologic–anemia and Felty's syndrome (splenomegaly and neutropenia); Cardiac–pericarditis and myocarditis; Neurologic–myelopathies secondary to cervical spine disease, entrapment and vasculitis.

Study objectives

1. To evaluate the safety of Unani Pharmacopoeial formulation – Habb-e-Irq un Nisa in patients of Waja'al-Mafasil.
2. To validate the efficacy of Unani Pharmacopoeial formulation – Habb- e-Irq un Nisa in patients of Waja'al-Mafasil.

Study design

An open-label clinical study conducted.

Overview of the study design

This study is designed as an open-label, multi-centric clinical trial in patients with Waja'al- Mafasil (Rheumatoid arthritis). The patients will be subjected to screening. After screening, patients suitable for participation in the study will receive Unani pharmacopoeial formulation Habb- e-Irq un Nisa daily with water after meals in the prescribed dose. The total duration of treatment will be 12 weeks. All clinical

follow-ups will be done once every 2 weeks. The laboratory investigations will be conducted at baseline and end of treatment (12 weeks) as per the CRF.

Methodology

Each participant will be well informed about the study and provided a participant information sheet (PIS); a written informed consent will be obtained before initiation of any study related procedure. Demographic data and information on the present disease condition, concomitant disease and therapy will be recorded. Thorough general physical and systemic clinical examination will be carried out. Signs and symptoms pertaining to Waja'al-Mafasil (Rheumatoid arthritis) will be recorded in the CRF. Vital signs including blood pressure, heart rate, temperature and respiratory rate will be noted. X-ray of affected joint will be conducted and blood samples will be collected for the evaluation of 2 laboratory parameters including, CBC, RF, ACPA, LFTs, KFTs, and Fasting Blood Glucose to establish and confirm Inclusion and Exclusion criteria. The follow-ups for clinical parameters will be done once in 2 weeks during treatment. Post-treatment follow-up will be conducted monthly for 2months.

Selection criteria

Inclusion criteria

1. Patients of either sex in the age group 18-65years.
2. Patients having Waja'al-Mafasil (rheumatoid arthritis) as defined by the following ACR-EULAR criteria (Annexure IV):
3. Definite clinical synovitis (pain, swelling, tenderness) in at least 1joint
4. Absence of an alternative diagnosis for the observed synovitis (arthritis)
5. A total score of at least 6 from the individual scores in 4 domains:
6. Number and site of involved joints (Range 0-5)

a) Serological abnormalities (Range 0-3)
b) Elevated acute-phase reactants (Range 0-1)
c) Duration of symptoms (Range 0-1)

Exclusion criteria

1. Rheumatoid arthritis with extra-articular manifestations, joint deformities, and advanced radiological lesions (e.g. joint subluxation and collapse).
2. Obese subjects (BMI≥30)
3. History or clinical evidence of any systemic inflammatory condition other than RA such as, juvenile chronic arthritis, spondyloarthropathy, IBD, psoriatic arthritis, active vasculitis, or gout that may interfere with evaluation.
4. Known case of any serious systemic illness, DM, TB, disseminated/ complicated Herpes Zoster (e.g., multi-dermatomal involvement, ophthalmic zoster, CNS involvement, or post-herpetic neuralgia), HIV infection or any other serious and/ or unstable illness that, in the opinion of the investigator, could constitute a risk when taking study drug or could interfere with the interpretation of data.
5. Screening laboratory test values, including SGOT, SGPT, ALP, S. creatinine, B. urea, and S. uric acid outside the reference range (raised >3 times the ULN) that, in the opinion of the investigator, could pose an unacceptable risk to the participant.
6. History of hypersensitivity to study drug or any of its ingredients.
7. Pregnant and lactating women
8. H/o Addiction (alcohol, drugs)

Subject selection

The patients of Waja'al-Mafasil (Rheumatoid arthritis) attending the O.P.D. of institute selected for the study. A detailed clinical history will be taken and complete physical examination will be carried out to make the clinical diagnosis of Waja'al-Mafasil, then the Laboratory investigations will be conducted to fulfill the ACR-EULAR criteria.

ACR-EULAR rheumatoid arthritis classification criteria

1. Definite clinical synovitis (pain, swelling, tenderness) in at least 1joint
2. Absence of an alternative diagnosis for the observed synovitis (arthritis)
3. A total score of at least 6 from the individual scores in 4 domains:
4. Number and site of involved joints (range 0-5)

a) Serological abnormalities (Range 0-3)
b) Elevated acute-phase reactants (Range 0-1)
c) Duration of symptoms (Range 0-1)

Unani pharmacopoeial formulation Habb-e-Irq un Nisa e prepared in a single batch at the Council's drug manufacturing Unit at CRIUM, Hyderabad and made available to the respective centers. All study drugs will be kept in a secure place under adequate storage conditions – protected from moisture. The drug can be stored at room temperature. The study participants will be dispensed drug for 2 weeks at a time with instructions to return the unconsumed drug (if any) at the next visit. This procedure has to be repeated for the whole duration of the study. Each 2 weeks' supply of drug comprising 1pack of Habb-e-irq un Nisa dispensed in sealed plastic containers.

Concomitant therapy

No concomitant therapy will be allowed during the study. However, rescue medication may be permitted and tablet count will be recorded in the CRF.

Assessment of mizāj (Temperament)

Assessment of Mizāj (Temperament) will be done at baseline and at the end of treatment (Annexure-III). 3

Follow-up evaluation

The patients will be assessed clinically at every 2 weeks, i.e., at days 14, 28, 42, 56, 70 and 84
The subjective and objective clinical observations recorded in the follow up sheet.

Re-scheduling follow-up visits

If any follow-up visit is missed, the visit will be rescheduled as soon as possible within an interval of +/ – 1week.

Follow-up after treatment

After completion of protocol therapy the clinical follow-up will be carried out monthly for 2 months

Laboratory investigations

Each case of Waja'al-Mafasil (rheumatoid arthritis) selected

for the study will be subjected to the following radiological, pathological and biochemical investigations at baseline and at the end of treatment and the reports received from the laboratory will be attached to the CRF.

Radiological investigation: X-Ray of affected joints

Pathological investigations
- CBC, Hb%, TLC, DLC, ESR
- Urine Examination: Routine &Microscopic

Biochemical investigations
- Liver Function Tests (LFTs): S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase
- Kidney Function Tests (KFTs): Serum Creatinine, Blood Urea, Serum Uric Acid
- Rheumatoid Factor (Quantitative Test)
- ACPA (Quantitative Test): in Rheumatoid Factor-negative cases only
- C-Reactive Protein (CRP): in cases with normal ESR only
- Fasting Blood Glucose (at Baseline only)

Assessment of safety
Clinical parameters
- Adverse Events(AEs)

Laboratory parameters
- CBC: Hb%, TLC, DLC, ESR
- LFTs: S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase
- KFTs: B. Urea, S. Creatinine, S. Uric Acid
- Urine Examination: Routine &Microscopic

Assessment of efficacy
In this clinical study, the VAS (0-100 mm) for joint pain, DAS28 (0-10) for clinical disease activity and reduction in the percentage of usage of rescue medicine will be used as a measure of improvement in RA to evaluate the efficacy of study drug.

Assessment of subjective parameters
The following subjective parameters will be graded as under
Joint tenderness: Nil/ Mild/ Moderate/ Severe
1. Mild: elicited on much pressure
2. Moderate: elicited on moderate pressure
3. Severe: elicited even on slight touch (patient does not allow to touch)

Joint swelling: Nil/ Mild/ Moderate/ Severe 0 =Nil
1. Mild: feeling of swelling with heaviness of joint
2. Moderate: apparent swelling
3. Severe: huge swelling

Early Morning Stiffness (EMS): Nil/ Mild/ Moderate/ Severe 0 =Nil
1. Mild: morning stiffness of 15-30 minutes duration
2. Moderate: morning stiffness of >30 &<60 minutes duration
3. Severe: morning stiffness of >60 minutes duration

Restriction of joint movement: Nil/ Mild/ Moderate/ Severe 0 =Nil
1. Mild: <25% restriction of movement
2. Moderate: 25-50% restriction of movement
3. Severe: >50% restriction of movement 4

Assessment of functional capacity
The simple classification for assessment of functional capacity in RA is as follows:
1. Class I Restriction of ability to perform normal activities.
2. Class II: Moderate restriction, but with an ability to perform most activities of daily living (ADL).
3. Class III: Marked restriction, with an inability to perform most activities of daily living (ADL) and occupation.
4. Class IV: Incapacitation with confinement to bed or a wheelchair.

Statistics
Description of Statistical Method
The data obtained will be analyzed statistically to evaluate the significance of the results. Descriptive statistics, Paired "t" test and ANOVA test with repeated measures will be applied for continuous quantitative variables. Non-parametric test like Friedman test will be applied for nominal and ordinal qualitative variables. Significance level. The significance level of $P < 0.05$ & < 0.001will be used in this study.

Study drug management
The following Unani pharmacopoeial formulation will be used in this study:

Table: The study drug Habb-e-Irq un Nisa is administered in tablet form (2 tablets, 800mg each), taken thrice daily orally with water after meals.

Study drug	Dosage form	Dose	Frequency	Route of administration	Method of administration
Habb-e-Irq un Nisa	Tablet	2Tablets 800mg each	Thrice daily	Oral	To be taken with water after meals

Details of investigational drug

Table: lists three ingredients: Sibr (Aloe Barbadensis), Post Halela Zard (Terminalia Chebula), and Suranjan Shireen (Colchicum Luteum), each with a quantity of 3.5 g

S. No.	Ingredients	Botanical Name	Quantity
1.	Sibr	Aloe Barbadensis	3.5 g
2.	Post Halela Zard	Terminalia Chebula	3.5 g
3.	Suranjan Shireen	Colchicum Luteum	3.5 g

(NFUM, Part-III, p. 17)

Ethical approval

Written approval of the study will be obtained from institutional ethics committee (IEC) prior to the study starting.

Approval letter must contain the following information:

a) Name and address of the ethics committee.
b) Date of the meeting.
c) Information that identifies the version of both the protocol and the subject.
d) information/informed consent.
e) Details of any other documents reviewed.

After obtaining ethical approval the trial registered at CTRI, centrally at Headquarters. The PI is required to submit the requisite documents to the Headquarters

Assessment of result

Age and response

In the table 1, the study shows that this is very common in the age group of 21 to 40 years as out of 90 cases studied maximum 34 cases were belonging to 31-40 age, followed by 21 cases in the age group of 21-30 years.05cases were 51-60 years age group and 2 cases were above 60 years age. As per response is concerned, good response observed in the age group of 31-40 years as out of 34 cases belonging to this group 12 cases got complete remission, 21 cases got partial remission and 01 case In the table -6, the study shows that this is very common in the age group of 21 to 40 years as out of 90 cases studied maximum 34 cases were belonging to 31-40 age, followed by 21 cases in the age group of 21-30 years.05cases were 51-60 years age group and 2 cases were above 60 years age. As per response is concerned, good response observed in the age group of 31-40 years as out of 34 cases belonging to this group 12 cases got complete remission, 21 cases got partial remission and 01 case got poor remission. In the age group 21-30 years 12 cases got complete remission 09 cases were partial remission.

Table 1: Response according to age group

Age group (In years)	Response			Total (%)
	Complete remission	Partially remission	Poor remission	
Up to 20	05	03	-	08(8.89)
21-30	12	09	-	21(23.3)
31-40	12	21	01	34 (37.78%)
41-50	10	10	-	20 (22.22%)
51-60	03	02	-	05 (5.55%)
Above 60	01	01	-	2 (2.22%)
Total (%)	43 (51.11%)	46 (51.11%)	01 (1.11%)	90 (100%)

Sex and response

In the table -2, the study shows that this disease is six times more common in females than males as out of 90 cases studied 77 were female and only 13 cases were males. As per response concerned, drug is somewhat equally effective in both the sexes, out of 77 females cases 38 cases got complete remission,38 cases got partially remission and 1 case got poor remission. While in 13 males cases, 5 cases got complete remission, 08 cases got partial remission.

Table 2: Response according to sex of patients

Sex	Response			Total (%)
	Complete remission	Partially remission	Poor remission	
Female	38	38	01	77
Male	05	08	00	13
Total (%)	43	46	01	90

Social status and response

Study also shows that out of 90 cases, 25 cases from lower income group, followed by 64 cases from middle income group and only 1 case from higher income group. As per income group and response of the drug concerned, good response recorded in MIG as out of 64 cases, 34 cases got complete remission, 30 cases got partial remission. In LIG out 25 cases studied 8 cases got complete remission, 16 cases got partial remission and 1 case got poor remission. In HIG group, out of 1 case studied, 1 case got complete remission.Table-3.

Table 3: Response according to social status of patients

Social Status	Response			Total (%)
	Complete remission	Partially remission	Poor remission	
Lower Income Group	08	16	1	25 (27.78%)
Middle Incom Group	34	30	-	64 (71.11%)
Higher Income Group	01	-	-	01 (1.11%)
Total (%)	43 (51.11%)	46 (51.11%)	1 (1.11%)	90 (100%)

Dietary habits and response

Data projected from study also shows that it is higher in non-vegetarian than vegetarian and out of 90 cases studied 33 cases were vegetarian and 57 non- vegetarian. As per response concerned, good response recorded in vegetarian, out 33 vegetarian cases 22 got complete remission and 10 cases got partial remission,1 case got poor remission. Likewise, 57 non-vegetarian cases, 26 cases got complete remission, 31 cases got partial remission and only case got poor remission as presented in table -4.

Table 4: Response according to dietary habits

Dietary Habits	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
Vegetarian	22	10	1	33 (36.67%)
Non- vegetarian	26	31	-	57 (63.33%)
Total (%)	48 (47.78%)	41 (51.11%)	1 (1.11%)	90 (100%)

Chronicity and response

Study data shows that maximum cases were having chronicity up to 2 years, out of 56 cases 28 cases got complete remission 28 cases got partially remission and followed by 15 cases got having chronicity 2-4 years 7 cases got complete remission, 8 cases got partially remission, 4-6 years 8 cases, 6-8 years 4 cases, 8-10 years 01 cases and above 10 years 6 cases. As chronicity and response of the formulae concerned, it is effective in the cases having chronicity up to 4 years and 6 cases having above 10 years chronicity 4 cases got complete remission, 2 cases got partially remission Table-5.

Table 5: Response according to chronicity of the disease

Chronicity	Response			Total (%)
	Complete Remission	Partially Remission	Poor Remission	
Up to 02 year	28	28	-	56 (62.22%)
02-04 year	7	8	-	15 (16.67%)
04-06 year	2	5	1	8 (8.89%)
06-08 year	2	2	-	4 (4.44%)
08-10 year	-	1	-	1 (1.11%)
Above 10 year	4	2	-	6 6.67%)
Total (%)	43 (47.78%)	46 (51.11%)	1 (1.11%)	90 100%

Temperament and response

The data shows that out of 90 cases studied maximum 32 cases having Balghami temperament followed by 3 cases Saudavi, 54 Safravi and 1 Damvi case. As per temperament and response of the formulae concerned, it is more effective in Balghami, Safravi temperament as out of 54 Safravi 27 cases got complete remission, 26 cases got partially remission and 1 got poor response. In Balghami 13 cases got complete remission and 19 cases got partially remission. In Saudavi 2 case got complete remission, 1 cases got poor and Damvi temperament only case got completly remission as presented in table-6.

Table 6: Response according to Mizaj (Temperament)

Mizaj (Temperament)	Response			Total (%)
	Complete remission	Partially remission	Poor remission	
Balghami	13	19	-	32 (35.55%)
Saudavi	2	1	-	3 (3.33%)
Safravi	27	26	1	54 (60%)
Damvi	1	-	-	1 (1.11%)
Total (%)	43 (47.78%)	46 (51.11%)	01 (1.11%)	90 100%

Conclusion

The study reveals that result of the Unani Pharmacopoeial Formulation – Habb-e-Irq un Nisa in Waja'al-Mafāsil (Rheumatoid Arthritis) effective, as out of 90 cases studied 43 cases got complete remission, 46 cases got partial remission and 01 cases got poor remission. The formulae reduced signs and symptoms like pain, tenderness, swelling, loss of functions and morning stiffness in uniform way. During the study blood investigations of each patient for CBC, liver function test, kidney function test, Rheumatoid factor, C- reactive protein were done at base line, monthly follow up and after completion of study.

We found that there was no significant effect of formulae on RA factor after completion of study, however there was slight increase in Hb% and marked decline ESR in well responded cases.

No Toxicity and adverse effect of the drugs reported during the study. Blood investigations done to observe any hepatic or renal toxicity at baseline, during follow up and after completion of study. It is observed that drug is safe and has no toxic effect on liver and kidney.

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