Management of Acute Gouty Arthritis with a Polyherbal Unani Formulation

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Abstract

Gout is one of the most common types of inflammatory joint diseases; affects an estimated 1-1.5% of the world population. Modern drugs used for subsiding acute attacks or lowering serum uric acid are associated with potent adverse effects. Moreover, these commonly used therapeutic agents often, and for various reasons, do not achieve the desired lowering of serum urate levels to below 6.0 mg/dl. On the basis of conventional Unani Usool-e-Ilaj of Niqris (gout), five herbal drugs from the list of classical Unani anti-arthritic drugs have been selected and formulated in capsule form and a single blind placebo controlled clinical trial was carried out to evaluate the efficacy and safety of this capsule in the management of gouty arthritis. Six week treatment with test drug produced remarkable effects on various efficacy parameters. No any adverse effect was observed during the course of treatment.

Keywords: Gout, Niqris, Wajaul Mafasil, Suranjan, *Cocchicum luteum*

Introduction

Gouty arthritis is among the earliest diseases that have been recognized as a clinical entity. First identified by the Egyptians in 2640 BC, podagra (acute gout occurring in the first metatarsophalangeal joint) was later recognized by Buqrat in the fifth century BC, who referred to it as 'the unwalkable disease. Buqrat also noted the link between the disease and an intemperate lifestyle, referring to podagra as'arthritis of the rich', as opposed to rheumatism, an 'arthritis of the poor'(Nuki *et al.*, 2006). Six centuries later to Buqrat, Jalinoos was the first to describe tophi (James *et al*., 2000).

Gout is one of the most common types of inflammatory joint diseases; affects an estimated 1-1.5% of the world population (Praveen *et al*., 1994). The prevalence of gout is rising as a result of a changing pattern of lifestyle (Arromdee *et al*., 2002). In most cases, no identifiable underlying cause of gout is present, but evident factors are usually present that could contribute to increase in urate (uric acid) levels, such as renal function disorders, obesity, and the use of thiazide diuretics (Roubenoll, 1990). Although, hyperuricemia is a risk factor for the development of gout, the exact relationship between hyperuricemia and acute gout is unclear. Acute gouty arthritis can occur in the presence of normal serum uric acid concentrations. Conversely, many persons with hyperuricemia never experience an attack of gouty arthritis (McCarty, 1994).

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Several approaches to the treatment of gout are available depending on the patient's presentation of the disease, patient's specific risk factors (high serum urates, previous attacks and radiographic signs), the clinical phase of the disease (acute, recurrent, tophaceous) and general risk factors, such as obesity and alcohol consumption.

Acute gout is usually treated by reducing inflammation of the affected joint with non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, corticosteroids etc. Although these agents are generally effective, they also present significant risks in patients who have pre-existing renal, cardiovascular, metabolic and gastrointestinal diseases (Nuki, 1999; Emmerson, 1996).

Antihyperuricemic drugs such as allopurinol, benzbromarone, sulfinpyrazone and probenecid can have potent side effects (Singer *et al.*, 1986, Arellano *et al.*, 1993). Benzbromarone was withdrawn from the market in Europe in 2003, but was registered again in some countries in 2004 (Sutaria *et al.*, 2006). Its use is now restricted for patients with gout who are allergic to allopurinol or those in whom allopurinol is contraindicated (Jansen *et al*., 2004). Furthermore, these commonly used therapeutic agents often, and for various reasons, do not achieve the desired lowering of serum urate levels to below 6.0 mg/dl.

The side effects/drawbacks of all above mentioned drugs call for the development of novel drugs with similar or better efficacy and lesser toxicity than presently available drugs.

On the basis of conventional Unani Usool-e-Ilaj of Niqris (gout), five herbal drugs from the list of classical Unani anti-arthritic drugs have been selected and formulated in capsule form and a clinical trial was carried out to evaluate the efficacy and safety of this capsule in the management of gout.

Materials and Methods

Study Drug

Study drug was a combination of five herbs namely, Suranjan (*Colchicum luteum*), Elva (*Aloe barbadensis*), Qurtum (*Carthamus tinctorius*), Halaila-e-Zard (*Terminalia chebula*), Zanjbeel (*Zingiber officinale*). All these five drugs in equal proportion were finely powdered and encapsulated in hard gelatin capsule in the quantity of 1gm.

Placebo

Placebo was supplied to the patients in the form of similar capsules of 1gm each containing wheat flour.

Study Design

This was a randomized, single blind, placebo controlled study, conducted in the Department of Moalejat, A & U Tibbia College & Hospital, Karol Bagh, New Delhi, From September 2009 to December 2011.

Participants

(i) Inclusion Criteria

Both male and female patients aged between 18 -65 years fulfilling the criteria of American College of Rheumatology (ACR) for diagnosing acute gouty arthritis including clinical features, laboratory and radiographic findings were included in the study, who had serum uric acid level more than the upper limit of normal range (> 7 mg/dl)

(ii) Exclusion Criteria

Patients were excluded if they had renal or hepatic insufficiency or cardiovascular disorders. Patients taking thiazide group of diuretics/ aspirin/NSAIDs and Pregnant and lactating women were too excluded from the study.

Ethical Consideration

All patients were included in the study after obtaining written informed consent and study was conducted according to Good Clinical Practice guidelines.

Dosage and Administration

Following 5-7 days washout period of anti-inflammatory/ analgesic drugs (e.g., NSAIDs, Corticosteroids) or antihyperuricemic drugs (eg allopurinol) or any other medication used for the treatment of arthritis (e.g. Ayurvedic, Homeopathic or Unani drugs), patients were randomly assigned to receive either drug or placebo capsule in the dose of 2 capsule thrice daily with plain water up to a period of six weeks. Randomization was done by lottery method.

Follow up and Drug Compliance

Clinical as well as laboratory evaluation was performed and recorded at the baseline, week 1, week 4 and week 6. Compliance with treatment drug/placebo was evaluated at each follow up visit by capsule count.

Criteria for the Assessment of Efficacy

To assess the response of treatment on patients of gouty arthritis in both groups, the following parameters were used.

Subjective Parameters

- Pain (Wong-Baker's Faces rating scale; with 0=doesn't hurt, 2=hurts a little bit, 4=hurts a little more, 6=hurts even more, 8=hurts a lot, 10=as much as the patient can imagine), (Cheng *et al.*, 2004; Taylor *et al.*, 2007).
- Tenderness (0-4 point scale; with 0=no tenderness, 1=patient says it is painful, 2=patient says it is painful, winces, and pulls back, 4=patient does not allow palpation), (Cheng *et al.*, 2004; Taylor *et al*., 2007).
- Joint swelling (0-4 point scale; with 0=no swelling,1=barely perceptible, 2=mild, 3=moderate, 4=severe, bulging beyond the joint margins) (Cheng *et al*., 2004; Taylor *et al*., 2007).
- Movement/Mobility (0-4 point scale; with 0=full voluntary movement,1=partial voluntary movement, 2=full movement when the joint is moved by the examiner, 3=partial movement when the joint is moved by the examiner, 4=no movement at all)
- Serum uric acid, C-Reactive proteins, Erythrocyte Sedimentation Rate and total leukocyte count

Assessment of Safety

To establish the safety of test drug , the following investigations were carried out at baseline, after one week and just after the termination of treatment.

- Liver function test –S.Bilirubin, S.G.O.T, S.G.P.T. & S.Alkaline Phosphatase
- Kidney function test – Blood Urea, S. Creatinine.
- Haemogramme – Hb%, TLC, DLC, E.S.R.

Statistical Analysis

The differences in pretreatment and post treatment obtained in both groups (test group and control group) were compared by applying Mann-Whitney U Test.

Results

Total 46 cases, 21 in test group and 25 in control group were randomly enrolled in the study. Two subjects from test group and 4 patients from control (placebo) group dropped out of the study due to unknown reason. Twenty patients in test group and 20 in control group completed the treatment up to the end of study (6 weeks).The demographic data and other characteristics at baseline are presented in Table 1.

Table 1: Demographic Data Baseline Characteristics of Study Patients

Variable		Test Group (N=20)	Control Group (N=20)
Age (Years) Mean ± SD		42.70 ± 11.15	43.80± 9.28
Gender	Male- N (%)	14 (70%)	15(75%)
	Female-N (%)	06 (30%)	05 (25%)
Family H/o Gout-N (%)		2 (10%)	3 (15%)
Pain Score (Mean ± SD)		5.95 ± 1.54	5.95 ± 1.50
Tenderness (Mean ± SD)		2 ± 1.12	1.60 ± 1.14
Swelling (Mean ± SD)		2.20 ± 0.95	1.55 ± 0.94
Movement (Mean ± SD)		1.70 ± 0.86	1.40 ± 0.59
S. Uric Acid		8.04 ± 1.98	7.81 ± 0.91
C.R.P.		3.92 ± 2.35	4.37 ± 2.18
T.L.C.		9300 ± 1554.6	8785 ± 1786.3
E.S.R.		26.65 ± 10.49	28.70 ± 11.3

SD = standard deviation; ESR = erythrocyte sedimentation rate;
CRP = C-reactive proteins; TLC= total leukocyte count

The effects of 6 weeks treatment with test drug and control on various clinical and laboratory parameters are described below:

Clincal Findings

Joint Pain

In test group, the mean score of pain (± SD) at baseline was 5.95 ± 1.54, which was reduced to 4.50 ± 1.91 on the 7th day, 3.30 ± 1.72 on 28th day and 1.85 ± 1.98 on the termination of treatment (42nd day). While in control group, the mean pain score was 5.95 ± 1.50 at baseline, which gradually increased to 6.05 ± 1.47 on 7th day, 6.0 ± 1.07 on 28th day, and 6.35 ± 1.23 at the end of treatment. On applying Mann- Whitney test, extremely significant difference between the two groups was detected on 28th day ($p<0.0001$) and 42nd day ($p<0.0001$), (Table-2).

Joint Tenderness

In test group the baseline tenderness score (mean ± SD) of 2.0 ± 1.12 decreased to 1.75 ± 0.97 (7th day), 1.05 ± 0.94 (28th day) and 0.60 ± 0.59 (42nd day). Whereas, there was very gradual and insignificant decrease in mean tenderness score in control group, from baseline (1.60 ± 1,14) to 1.50 ± 1 on 7th day, 1.55 ± 0.99 on 28th day, 1.50 ± 0.21 on termination of

Table 2: Effect of Test Drug and Control on Pain

Pain	Control Group (N=20)				Test Group (N=20)			
	0 day	7th day	28th day	42nd day	0 day	7th day	28th day	42nd day
Mean	5.95	6.05	6.0	6.35	5.95	4.50	3.30	1.85
S.D. (±)	1.50	1.47	1.08	1.23	1.54	1.90	1.72	1.99
S.E.M. (±)	0.34	0.33	0.24	0.28	0.34	0.43	0.38	0.44
% change	-	1.68	0.84	6.72	-	24.36	46.9	68.91
P value at 7th day (T/C) <0.01 (LS) (Mann-Whitney Test) P value at P value 28th day (T/C) <0.0001 (ES) (Mann-Whitney Test) P value 42nd day (T/C) <0.0001(ES) (Mann-Whitney Test)								

SD = Standard Deviation,; S.E.M. Standard Error of Mean; LS = Less Significant, HS = Highly Significant

treatment. The difference in tenderness in between the groups as analysed by Mann-Whitney Test was not significant at 28th day ($p>0.05$) and moderately significant at 42nd day ($p<0.01$), (Table-3).

Joint Swelling

In Placebo group, the mean score of swelling increased from 1.55 ± 0.94 (baseline) to 1.70 ± 0.98 on 7th day, 1.70 ± 0.98 on 28th day and1.75 ± 1.02 on 42nd day. On the other hand the mean score of swelling at baseline in test group was 2.20 ± 0.95, 1.80 ± 0.83 on 7th day, 1.15 ± 0.67 on 28th day, and 0.45 ± 0.51 on 42nd day. The difference in between the groups as analysed statistically was found to be non-significant ($p>0.05$) on 7th day & 28th day, but extremely significant on 42nd day ($p<0.001$), (Table-4).

Table 3: Effect of Test Drug and Control on Tenderness

Tenderness	Control Group (N=20)				Test Group (N=20)			
	0 day	7th day	28th day	42nd day	0 day	7th day	28th day	42nd day
Mean	1.60	1.50	1.55	1.50	2	1.75	1.05	0.60
S.D. (±)	1.14	1.0	0.99	0.94	1.12	0.97	0.94	0.59
S.E.M. (±)	0.25	0.22	0.22	0.21	0.25	0.22	0.21	0.13
% change	-	6.25	3.12	6.25	-	12.5	47.5	70
P value at 7th day (T/C) 0.48 (NS) (Mann-Whitney Test) P value at 28th day (T/C) 0.12 (NS) (Mann-Whitney Test) P value at 42nd day (T/C) 0.003 (MS) (Mann-Whitney Test)								

SD = Standard Deviation; S.E.M. Standard Error of Mean; LS = Less Significant, NS Not Significant; MS = Moderately Significant

Table 4: Effect of Test Drug and Control on Swelling

Joint Swelling	Control Group (N=20)				Test Group (N=20)			
	0 day	7th day	28th day	42nd day	0 day	7th day	28th day	42nd day
Mean	1.55	1.55	1.70	1.75	2.20	1.80	1.15	0.45
S.D. (±)	0.94	0.94	0.98	1.02	0.95	0.83	0.67	0.51
S.E.M. (±)	0.21	0.21	0.22	0.23	0.21	0.18	0.15	0.11
% change	-	0	9.68	12.9	-	18.18	47.73	79.54
P value at 7th day (T/C) 0.44 (NS) (Mann-Whitney Test) P value at 28th day (T/C) 0.05(NS) (Mann-Whitney Test) P value at 42nd day (T/C) 0.0002 (ES) (Mann-Whitney Test)								

SD = Standard Deviation; S.E.M. = Standard Error of Mean; NS = Not Significant; ES = Extremely Significant

Restriction of Movements

In Control group, the mean score (± SD) of restriction in movements in control group was 1.40 ± 0.59 at baseline, 1.45 ± 0.60 at 7th day, 1.45 ± 0.60 at 28th day, 1.65 ± 0.74 at 42nd day. On the other hand, in test group the restriction of movement was 1.70 ± 0.86 (baseline), 1.35 ± 0.59(7th day), 0.85 ± 0.67 (28th day), and 0.55 ± 0.51 (42nd day).According to Mann-Whitney test, the difference in between the groups was moderately significant ($p<0.01$) on 28th day and extremely significant ($p<0.001$) on 42nd day (Table-5).

Table 5: Effect of Test Drug and Control on Restriction of Movements

Restriction of Movement	Control Group (N=20)				Test Group (N=20)			
	0 day	7th day	28th day	42nd day	0day	7th day	28th day	42nd day
Mean	1.40	1.45	1.45	1.65	1.70	1.35	0.85	0.55
S.D. (±)	0.59	0.60	0.60	0.74	0.86	0.59	0.67	0.51
S.E.M	0.13	0.13	0.13	0.17	0.19	0.13	0.15	0.11
% change	–	3.57	3.57	17.86	–	20.59	50	67.65
P value at 7th day (T/C) 0.61 (NS) (Mann-Whitney Test) P value at 28th day (T/C) 0.008(NS) (Mann-Whitney Test) P value at 42nd day (T/C) 0.0001 (ES) (Mann-Whitney Test)								

SD = Standard Deviation; S.E.M. = Standard Error of Mean;, NS = Not Significant; ES = Extremely Significant

Laboratory Findings

Serum Uric Acid

In control group, the mean values of serum uric acid were 7.81± 0.91 at baseline, 7.62 ± 1.13 mg/dl, 7.62 ± 1.14 mg/dl, 7.71 ± 1.82 mg/dl, on day 7th, 28th and 42nd respectively. On the contrary, in test group the change in the serum levels of uric acid decreased from baseline of 8.04 ± 1.98 mg/dl to 6.21 ± 1.62 mg/dl on 7th day, 6.27 ± 1.52 mg/dl on day 28 and 5.55 ± 1.57 mg/dl on day 42. The difference in mean values between the two groups on all the three follow ups was extremely significant ($p<0.001$) as analysed by using Mann Whitney U test (Table-6).

C - Reactive Protein

The C-Reactive protein values observed in test group were 3.92 ± 2.35 mg/dl at baseline 3.91 ± 2.17 mg/dl on 7th day, 2.99 ± 1.86 mg/dl on 28th day and 2.30 ± 1.42 mg/dl on 42nd Whereas, in control group the mean values of CRP were recorded as 4.37 ± 2.18 mg/dl at baseline, 4.30 ± 2.20 mg/dl on 7th day, 3.95 ± 2.14 mg/dl on 28th day and 3.70 ± 2.03 mg/dl on 42nd day. The inter-group difference was not significant ($p>0.05$) on day 7 and day 28, but was less significant ($p<0.05$) on day 42 (Table-7).

Total Leucocyte Count (T.L.C.)

In Control group, the mean TLC count in control group was 8080 ± 1395/mm^3 at baseline, 9105 ± 1325 /mm^3 on day 7th, 9180 ± 1405 /mm^3 on day 28th, and 8950 ± 1325/ mm^3 on day 42nd. While in test group it was recorded as 9300 ± 1554 mm^3/ 8080 ± 1395/ mm^3 on day 7th, 8380 ± 1505/ mm^3 on day 28th, and 7860 ± 1622/ mm^3 on day 42nd. The difference in between the group was

Table 6: Effect of Test Drug and Control on Serum Uric Acid

S. Uric	Control Group (N= 20)				Test Group (N=20)			
Acid (mg/dl)	0 day	7th day	28th day	42nd day	0 day	7th day	28th day	42nd day
Mean	7.81	7.62	7.62	7.71	8.04	6.21	6.27	5.55
S.D.(±)	0.91	1.13	1.14	1.18	1.98	1.62	1.52	1.57
S.E.M(±)	0.20	0.25	0.25	0.26	0.44	0.36	0.34	0.35
% change		2.43	2.43	1.28		22.76	22.01	30.97
P value at 7th day (T/C) 0.0008 (ES) (Mann-Whitney Test) P value at 28th day (T/C) 0.0007 (ES) (Mann-Whitney Test) P value at 42nd day (T/C) <0.0001 (ES) (Mann-Whitney Test)								

SD = Standard Deviation; S.E.M. = Standard Error of Mean; ES = Extremely Significant

Table 7: Effect of Test Drug and Control on C-Reactive Proteins

C-reactive protein (mg/dl)	Control Group (N= 20)				Test Group (N=20)			
	0 day	7th day	28th day	42nd day	0 day	7th day	28th day	42nd day
Mean	4.37	4.3	3.95	3.70	3.92	3.91	2.99	2.30
S.D.(±)	2.18	2.20	2.14	2.03	2.35	2.17	1.86	1.42
S.E.M(±)	0.48	0.49	0.48	0.45	0.52	0.49	0.42	0.32
% change		1.6	9.61	15.33		0.25	23.72	41.32
P value at 7th day (T/C) 0.33 (NS) (Mann-Whitney Test) P value at 28th day (T/C) 0.06 (NS) (Mann-Whitney Test) P value at 42nd day (T/C) 0.03 (LS (Mann-Whitney Test)								

SD= Standard Deviation; S.E.M..=Standard Error of Mean;, NS= Not Significant; LS= Less Significant

less significant ($p<0.05$) at day 7th, not significant ($p<0.05$) at day 28th,and again less significant($p<0.05$) at day 42nd (Table-8).

Erythrocyte Sedimentation Rate (E.S.R.)

In control group, E.S.R noted was 28.70 ± 11.33/1 hr at baseline, 29.45 ± 11.07/1 hr at 7th day, 29.75 ± 10.42/1 hr at day 28th and 30.10 ± 11.19/1 hr at 42nd day. On the other hand the E.S.R observed in test group was 25 ± 11.53/1 hr at 7th day, 25.30 ± 10.27/1 hr at 28th day, 22.30 ± 12.02/1 hr on 42nd day. The difference in ESR values between the two groups were a not significant ($p>0.05$) on 7th and 28th day, whereas mildly significant difference was observed ($p<0.05$) on 42nd day, (Table 9).

Table 8: Effect of Test Drug and Control on Total Leukocyte Count

T.L.C. (cu.mm)	Control Group (N=20)				Test Group (N=20)			
	0 day	7th day	28th day	42nd day	0 day	7th day	28th day	42nd day
Mean	8785	8080	8380	7860	9300	9105	9180	8950
S.D. (±)	1786.3	1395.7	1505.3	1622	1554.6	1325.3	1405.5	1325.7
S.E.M. (±)	399.43	312.09	336.59	362.69	347.62	296.34	314.27	296.43
% change	-	8.02	4.61	10.53	-	2.09	1.29	3.76
P value at 7th day (T/C) 0.01 (LS) (Mann-Whitney Test) P value at 28th day (T/C) 0.08 (NS) (Mann-Whitney Test) P value at 42nd day (T/C) 0.01 (LS) (Mann-Whitney Test)								

SD = Standard Deviation; S.E.M. = Standard Error of Mean; NS = Not Significant; LS = Less Significant

Table 9: Effect of Test Drug and Control on ESR

E.S.R. (mm/1sthr)	Control Group (N=20)				Test Group (N=20)			
	0 day	7th day	28th day	42nd day	0 day	7th day	28th day	42nd day
Mean	28.70	29.45	29.75	30.10	26.65	25.00	25.30	22.30
S.D. (±)	11.33	11.08	10.42	11.19	10.49	11.53	10.27	12.02
S.E.M. (±)	2.533	2.48	2.33	2.5	2.35	2.58	2.29	2.69
% change	-	2.61	3.65	4.88	-	6.19	5.06	16.32
P value at 7th day (T/C) 0.29 (NS) (Mann-Whitney Test) P value at 28th day (T/C) 0.27 (NS) (Mann-Whitney Test) P value at 42nd day (T/C) 0.02 (LS) (Mann-Whitney Test								

SD = Standard Deviation; S.E.M. = Standard Error of Mean; NS = Not Significant; LS = Less Significant

Safety

During the course of the study, no adverse events were reported by the patients or clinically detected by the investigator. No any significant change from base line was observed in haemoglobin, SGOT, SGPT, S.Bilirubin, B.Urea and S. Creatinine values in both the groups. The test formulation as well as placebo was found well tolerated as indicated by 85% drug compliance

Discussion

Gout is one of the most common types of inflammatory joint diseases, modern drugs used for subsiding acute attacks or lowering serum uric acid are associated with potent adverse effects. Furthermore, these commonly used therapeutic agents often, and for various reasons, do not achieve the desired lowering of serum urate levels to below 6.0 mg/dl. In the present study, the unani formulation consisting of Suranjan (*Colchicum luteum*), Elva (*Aloe barbadensis*), Qurtum (*Carthamus tinctorius*), Halaila-e-Zard (*Terminalia chebula*), Zanjbeel (*Zingiber officinale*) not only relieved various signs and symptoms of gouty arthritis but also exerted remarkable effects on lowering serum uric acid level and various other inflammatory markers. The relief in joint pain, tenderness can be attributed to the analgesic activity of

Suranjan (*Colchicum luteum*) (Hakeem, 1991; Rainsford, 1999), Elva (*Aloe barbadensis*) (Sharma *et al.*, 2002; Sheshadri, 1976) and Zanjbeel (*Zingiber officinale*) (Khare, 2004; Sharma *et al*, 2002). Anti-inflammatory activity of Qurtum (*Carthamus tinctorius*) (Linda, 2001), Halaila-e-Zard (*Terminalia chebula*) (Sharma *et al.*, 2002), Zanjbeel (*Zingiber officinale*) (Linda, 2001; Sharma *et al.,* 2002; Wagner *et al*.,1985) can also be considered in decreasing

pain, swelling and tenderness. Acute attack of gouty arthritis is initiated by the precipitation of urate crystals in the synovial fluid resulting in inflammatory response and the acute inflammatory cells (nutrophils) phagocytose urate crystals and release a glycoprotein which further aggravates inflammation. Colchicine, an active constituent of Suranjan (*Colchicum luteum*), has been proved inhibitory to the glycoprotein released by the nutrophils in acute gouty inflammation. Colchicine by binding with fibrillar protein tubulin has been found to inhibit nutrophil migration in the inflammed joint. All this explains relief in pain, swelling and tenderness because of Suranjan (*Colchicum luteum*) (Jean Brunneton, 1995; Robert *et al*., 1983). The diuretic activity of Qurtum (*Carthamus tinctorius*) (Kritikar & Basu, 1984) and laxative action of Halaila-e-Zard (*Terminalia chebula*) (Barthakur *et al.*, 1991) and Elva (*Aloe barbadensis*) (Blumenthal *et al*., 1998) might also be helpful in reducing monosodium urate precipitation by increased excretion of uric acid through urine and faeces respectively.

In the light of above discussion and on the basis of observations and results obtained in this study, large scale, standard control, double blind randomized clinical is warranted to further support the efficacy and tolerability of test formulation in the treatment of gouty arthritis.

Conclusion

Unani formulation produced remarkable effects on various efficacy parameters in cases of acute gouty arthritis. The drug was found safe and well tolerated, as no adverse events were reported by the patients or clinically detected by the investigator during the course of six week therapy.

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