

# Clinical Study on An Unani Formulation 'Qurs e Kushta Khabs al-Hadeed and Habb-e-Marwareed' in Sayalan-al-Rahim (Leucorrhea)"

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## Abstract

The objective of the study was to evaluate the safety and efficacy of Unani pharmacopoeial formulations viz. 'Qurs e Kushta Khabs Al-Hadeed and Habb-e-Marwareed' in Sayalan-al-Rahim (Leucorrhea). One tablet of both drugs were administered orally to the patients, twice daily for 4 weeks. After the treatment, mean  $\pm$  S.E.M. scores of clinical parameters of the disease including the amount of vaginal discharge, general weakness, backache, anaemia, excoriation and ulceration were subsided by 43.36% ( $p<0.001$ ), 60.64% ( $p<0.001$ ), 30.02% ( $p<0.001$ ), 50.81% ( $p<0.001$ ), 48.15% ( $p<0.001$ ) and 44.26% ( $p<0.001$ ) respectively as compared to the baseline. No adverse effect of the study drugs was found on the bio-chemical parameters of liver and Kidney function test. No adverse event was found either volunteered by the patients or elicited by the investigator by clinical as well as by laboratory investigations at the baseline and after the treatment. The Unani formulations Qurs e Kushta Khabs Al-Hadeed and Habb-e-Marwareed were found clinically very effective and safe in the treatment of Sayalan-al-Rahim (Leucorrhea).

**Keywords:** Qurse e Kushta Khabs Al-Hadeed and Habb-e-Marwareed, Unani formulation, Sayalan-al-Rahim.

## Introduction

Sayalan-al-Rahim (Leucorrhea) is an excessive vaginal discharge which may be whitish, yellowish or greenish in colour. It is a frequent gynecological complaint of women and accounts for more than 1/4<sup>th</sup> gynaec patients who visit gynecologists (Dutta, 2007; Sabaratnum *et al.*, 1993). Peculiar vaginal discharge is generally associated with body ache and thirst (Yudin *et al.*, 2003). The most common cause of leucorrhea is physiological followed by vaginal infections due to bacteria, virus, fungi and parasites. Other causes include foreign bodies, cervicitis and atrophic vaginitis (Pravina, *et al.*, 1991). Sometimes, symptoms of disease are so severe that it over shadows the actual disease and women seek treatment only for symptoms (Sutton *et al.*, 2007; Johnston *et al.*, 2008).

The Unani scholars have described Sayalan-al-Rahim (Leucorrhea) and its treatment in various Unani classical literature like Kamil al Sana'a, Al Hawi, Firdaus al Hikmat and Tibb-e-Akbar etc. According to them, disease is due to poor quwwat-e-ghadhiya (nutritive faculty) of the rahim (uterus) that causes accumulation of fuzlaat (waste materials) (Kabiruddin, 2003). According to

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humoural theory, Sayalan-al-Rahim is caused by the excess of humours and is of four types; sayalan-al-rahim damwi, sayalan-al rahim-safrawi, sayalan-al-rahim balghmi and sayalan-al-rahim sawdavi with discharge colours reddish, yellowish, whitish and blackish respectively (Khan, 2010). Associated symptoms of the disease are excessive vaginal discharge, weakness, backache, pain in the thighs and calf muscles, burning micturition etc. (Kabiruddin, 2003; Khan, 2002).

The drugs available in modern medicine produces more or less adverse effects in the human body and therefore natural, herbal or traditional medicines are now being seen by the people with an eye of great interest and hope. Unani medicine is one of them that not only provides the drugs information in abundance but also claims that the drugs have least or no adverse effect.

The Unani physicians have used Unani pharmacopoeial formulations viz. Qurs e Kushta Khabs Al-Hadeed and Habb-e-Marwareed in the treatment of Sayalan al Rahim (Leucorrhea) since ages and the Unani drug and its formulations have been mentioned in various Unani literature (Khan, 2002; Jeelani, 2005). The Unani formulations and their compositions have also been mentioned in National Formulary of Unani Medicine for treatment of Sayalan-al-Rahim (Leucorrhea) (Anonymous, 1993) but the clinical data to prove that Qurs e Kushta Khabs Al-Hadeed and Habb-e-Marwareed are safe and efficacious in treatment of the disease are not available. The international community will accept this Unani formulation only if it satisfies the safety and efficacy norms set by the International Regulatory Authority (Shetti *et al.*, 2011), therefore, the present clinical study was conducted with an aim to assess the clinical efficacy and safety of 'Qurs-e-Khusta Khabs-al-Hadeed and Habb-e-Marwareed' in the treatment of Sayalan al Rahim (Leucorrhea).

## **Material and Methods**

### **Study Drugs**

The study drugs were two Unani formulations viz. Qurs e Kushta Khabs Al-Hadeed and Habb-e-Marwareed. The compositions are given in Table 1. The drugs manufactured by CRI, Hyderabad were supplied to the Regional Research Institute of Unani Medicine, Patna.

### **Study Design**

The study was designed as open-label multi centric clinical study.

### **Patients Selection**

Diagnosis of each case was made with the help of a detailed history in respect of the patients i.e. history and physical examination, allergic history and other systemic examinations as well as the laboratory investigations. The screened patients presenting one or more symptoms of Sayalan al Rahim (Leucorrhea), who met the inclusion criteria were selected for the study by Regional Research Institute of Unani Medicine, Patna, between August 2014 and March 2015.

### **Inclusion Criteria**

- Female patients in the age group of 14-45 years.
- Patients having excessive white discharge with symptoms like general weakness, backache, anaemia, excoriation or ulceration etc.
- Patients willing to sign an informed consent form to participate in the study.
- Patients willing to comply with various demands of the study.

### **Exclusion Criteria**

- Patients having acute/chronic PIDs.
- Patients on long-term medications.
- Patients on oral contraceptives / IUDs or taking hormonal therapy
- Pregnant and lactating women.
- Diabetes mellitus excluded by taking the history and blood sugar fasting examination.

### **Treatment of Patients**

The screened patients selected for the present study were given tablets of *Qurs-e-Kushta Khabs -al-Hadeed* (each tablet 100 mg) and *Habb-e-Marwareed* (each tablet 250 mg) with water after the meals; one tablet each of both the drugs twice daily for a period of four weeks. No concomitant treatment was given.

### **Clinical Evaluation**

The efficacy of Unani pharmacopoeial formulations viz. *Qurs e Kushta Khabs al-Hadeed* and *Habb e Marwareed* were assessed on clinical parameters of the Sayalan-al-Rahim (Leucorrhea) including the amount of vaginal discharge, general weakness, backache, anaemia, excoriation, ulceration etc. As, these clinical parameters differ in severity, such as absent, mild, moderate or severe

from patient to patient and therefore, severity of the clinical parameters including amount of vaginal discharge, anaemia, excoriation and ulceration were graded as absent=0, mild=1, moderate=2 and severe=3. General weakness and backache were assessed on a 10 point VAS for appropriate assessment and statistical evaluation of the efficacy of the study drugs. The patients were followed-up after 2 weeks and 4 weeks. And at every visit, they were clinically examined and asked about the improvement or worsening of their symptoms. Assessment of the temperaments of the patients was also done before and after the treatment.

### Safety Assessment

The safety was assessed by monitoring adverse events reported by the patients or elicited by the investigator by clinical as well as by laboratory investigations at the baseline and after the treatment. The laboratory tests included Haematological Test (Hb.%, TLC, DLC, ESR), Liver Function Test (Serum bilirubin, SGOT, SGPT, Alkaline phosphatase) and Kidney Function Test (Blood urea, Serum creatinine).

### Statistical Analysis

All the data were statistically analyzed by applying paired't' test to evaluate the efficacy and safety of the drugs. Probability level of less than 5% was considered as statistically significant.

### Results

The distribution of characteristics / demographic data of patients in accordance with their ages and marital status; chronicities and status of the disease; dietaries habits and temperaments and socio economic status are summarized in Table 2, Table 3, Table 4 and Table 5 respectively.

The efficacy of the study drugs on the clinical parameters of Sayalan-al-Rahim (Leucorrhea) are depicted in Table 6. After the treatment, mean  $\pm$  SEM scores of clinical parameters of the disease including the amount of vaginal discharge, general weakness, backache, anaemia, excoriation and ulceration were found decreased from  $2.56 \pm 0.06$ ,  $5.03 \pm 0.13$ ,  $5.23 \pm 0.12$ ,  $1.24 \pm 0.08$ ,  $0.81 \pm 0.11$  and  $0.61 \pm 0.10$  to  $1.84 \pm 0.05$ ,  $3.29 \pm 0.14$ ,  $4.29 \pm 0.15$ ,  $0.95 \pm 0.08$ ,  $0.58 \pm 0.09$  and  $0.44 \pm 0.07$  respectively. The reduction in Mean  $\pm$  SEM scores of the amount of vaginal discharge, general weakness, backache, anaemia, excoriation and ulceration were 43.36% ( $p<0.001$ ), 60.64% ( $p<0.001$ ), 30.02% ( $p<0.001$ ), 50.81% ( $p<0.001$ ), 48.15% ( $p<0.001$ ) and 44.26% ( $p<0.001$ ) respectively as compared to the baseline. No adverse effect was detected by clinical examination

and/or laboratory investigations.

The effects of the trial compound drugs on haematological parameters (HB, TLC, DLC and ESR) and bio-chemical parameters (Liver Function Test parameters and Kidney Function Test parameters), as assessed by the laboratory investigations are depicted in Table 7 and Table 8 respectively.

After the treatment, haemoglobin in blood was found significantly increased by 1.94 % ( $p<0.05$ ) as compared to the baseline. After the treatment, the variations in mean scores of other haematological parameters were found not significant as compared to the baseline (Table 7).

After the treatment, Mean  $\pm$  SEM scores of the markers of Lever function test i.e. Serum bilirubin, Serum glutamic oxaloacetic transaminase (SGOT), Serum glutamic pyruvic transaminase (SGPT), and Alk.Phosphatase (ALP) were reduced from  $0.79 \pm 0.03$ ,  $17.46 \pm 0.86$ ,  $22.9 \pm 1.75$  and  $6.67 \pm 0.31$  to  $0.76 \pm 0.02$ ,  $16.24 \pm 0.82$ ,  $18.9 \pm 1$  and  $5.96 \pm 0.31$  respectively; the percentage reduction in these L.F.T. parameters were 3.87% , 7.0%, 17.7% ( $p<0.05$ ) and 10.73% ( $p<0.05$ ) respectively as compared to the baseline (Table 8 ).

After the treatment, mean  $\pm$  SEM scores of renal markers i.e. S.creatinine, S.urea and S.uric acid were decreased from  $0.84 \pm 0.02$ ,  $24.12 \pm 0.68$  and  $3.08 \pm 0.11$  to  $0.77 \pm 0.01$ ,  $21.04 \pm 0.59$  and  $3.24 \pm 0.12$  respectively; the percentage reduction in these renal markers were 8.14% ( $p<0.05$ ), 12.75% ( $p<0.05$ ) and 4.75% respectively as compared to the base line (Table-8). During the course of the study, no adverse event was reported by the patients.

## Discussion

Analysis of the results of 62 cases of Sayalan-al-Rahim (Leucorrhea) treated with 'Qurs e Kushta Khabs al-Hadeed and Habb e Marwareed' have revealed some interesting facts which have been discussed as below:

- The present study has revealed that the disease is prevalent among women in 14-54 years of their age and the highest incidences of disease 46.78% was found in the mid reproductive age group of 25-34 years followed by 30.64% in the age group of 14-24 years (Table 2).72.58% of the patients were married and the remaining 27.42% unmarried. The married women have impact on the occurrence of vaginal discharge with active sexual life, which was also shown in another study conducted by Rice and schachter (Rice *et al.*, 1991).
- The incidence of the disease was observed maximum (72.58%) in the middle

income group. It may be due to the fact that most of the women in the middle income group are either employed in Government job or private sectors job where they have to work under stress and tension. Maximum mental tension in women of middle income group may be a perceived cause of the disease and is in accordance with the finding of Dash 1974 who has described the mental tension as a cause of this disease.

- The prevalence of Sayalan al Rahim (Leucorrhea) was more common among the females who are non-vegetarian (75.8%) as compared to safravi (biliary) (24.2%) temperament. This fact needs to be further studied by taking a large sample size (Table 4).
- The study disclosed that 67.80% cases were known. Data in Table 3 present the patients who had taken some treatment earlier for the disease in other system of medicines before coming to Unani system of medicines for treatment. This finding suggests that patients who were not getting any relief by other system of medicines came for treatment by Unani system of medicines. The present study further disclosed that 51.61% patients had this problem for more than one year. It may be due to the fact that lack of awareness among most of the women about the disease ignored the problem for a long period till it becomes chronic (Table 3).
- The study shows that clinical symptoms of the disease were subsided after the treatment with Qurs e Kushta Khabs al-Hadeed and Habb e Marwareed. After the treatment, the clinical parameters of the disease including vaginal discharge, general weakness, backache, anaemia, excoriation and ulceration were found significantly reduced by 43.36% ( $p<0.001$ ), 60.64% ( $p<0.001$ ), 30.02% ( $p<0.001$ ), 50.81% ( $p<0.001$ ), 48.15% ( $p<0.001$ ) and 44.26% ( $p<0.001$ ) respectively (Table-6). The result shows that Unani formulations Qurs e Kushta Khabs al-Hadeed and Habb e Ma rwareed are very effective to subside the associated symptoms of the disease. The clinical data of the present study prove the scientific justification of the traditional use of these Unani formulations in relieving the symptoms of Sayalan-al-Rahim(Leucorrhea)
- The present study exhibited that after the treatment, the change in haematological parameters like TLC, DLC and ESR were found not significant but haemoglobin was found significant as compared to the baseline ( $p<0.05$ ) (Table 7).
- The present study exhibited variations in S. Bilirubin and SGOT and found not

significant. Elevated level of SGPT and Alk. Phosphatise, which may cause malfunctioning of the livers in the patients were found reduced significantly by 17.7% and 10.73% respectively as compared to the baseline. It was also found that the mean scores of elevated level of renal markers viz. S. Creatine and S. Urea were reduced by 8.14% and 12.75% respectively. Elevated levels of S. Creatine and S. Urea in bloods which may cause malfunctioning of the Kidney were reduced after the treatment (Table 8).

Based on the findings it can be suggested that trial drugs were found very effective and safe in the treatment of Sayalan al Rahim (Leucorrhea).

### **Conclusion**

On the basis of the above observations, it can be concluded that the Unani formulations viz. Qurs e Kushta Khabs al-Hadeed and Habb e Marwareed are clinically effective and safe in the treatment of Sayalan al Rahim (Leucorrhea) and hence these can be prescribed to the patients in treatment of Sayalan al Rahim (Leucorrhea). These Unani formulations are cheap, easily available and can be easily tolerated by the patients without any adverse effect on them.

**Table 1:** Composition of 'Qurs e Kushta Khabs al-Hadeed and Habb e Marwareed'

<b>Unani Drugs</b>	<b>Constituents</b>	<b>Latin names</b>	<b>Quantity</b>
Habb e Marwareed	Mastagi	Pistacia lentiscus Linn.	120 gm
	Tankar neem biriyani	Sodium borate decahydrate	60 gm
	Mazu muhraq	Quercus infectoria olivier	60 gm
	Azraqi Mudabbar	Strychnox nux vomica Linn	60 gm
	Marwareed	Mytilus marginiferus	15 gm
	Ambar Ash-hab	Ambra grasea	15 gm
	Arq-e-Gulab	Rosa damascena Mill	Q.S.
Kusta e Khabs al-Hadeed	Constituents	Latin names	Quantity
	Khabs al Hadeed	Iron oxide ferric/ferous oxide	100 mg
	Sirka Naishakar	Malus domestica Syn. M.sylvestris	Q.S.
	Maghz e gheekawar	Aloe barbadensis Linn.	Q.S.
	Chaac	Whey	Q.S.

**Table 2:** Distribution of Patients According to Age and Marital Status

Age groups (in years)	Unmarried		Married		Total	
	No.	% age	No.	% age	No.	% age
14-24	15	24.19	04	6.45	19	30.64
25-34	02	3.23	27	43.55	29	46.78
35-44	00	00	12	19.35	12	19.35
45-54	00	00	02	3.23	02	3.23
Total	17	27.42	45	72.58	62	100

**Table 3:** Distribution According to Chronicity and Status of the Disease

Chronicity of disease	Status of disease				Total	
	New Status		Known status		No.	Percentage
	No.	Percentage	No.	Percentage		
Up to 1 Year	17	27.4	12	19.4	29	46.77
01-03 Years	03	4.8	22	35.5	25	40.32
03-05 Years	00	00.0	07	11.3	07	11.29
Above 5 Years	00	00.0	01	01.6	01	01.61
Total	20	32.2	42	67.8	62	100

**Table 4:** Distribution According to Dietary Habits and Temperament of the Patients

Temperament of patients	Dietary habits				Total	
	Veg.		Non-Veg.		No.	Percentage
	No.	Percentage	No.	Percentage		
Damvi (Sanguine)	03	4.8	08	12.9	11	17.7
Balghami (Phlegmatic)	04	6.5	15	24.1	19	30.6
Safravi (Bilious)	05	8.1	19	30.7	24	38.8
Saudavi (Melancholic)	03	4.8	05	8.1	08	12.9
Total	15	24.2	47	75.8	62	100

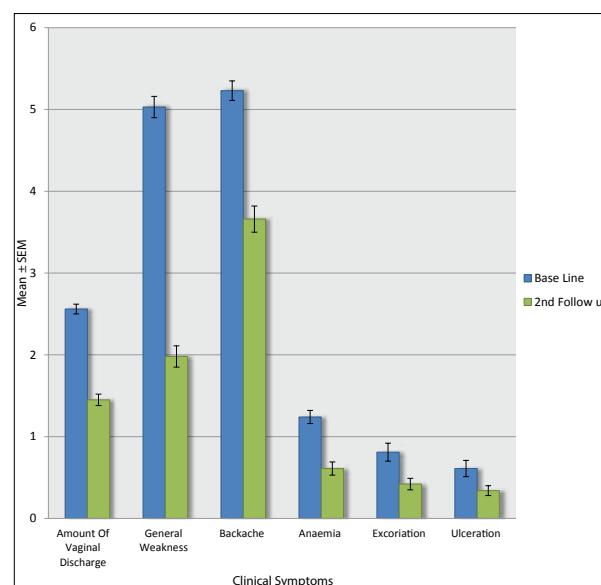
**Table 5:** Socio – Economic Status of the Patients

Socio Economic Status	No. of Patients	Percentage
Lower Income Group	11	17.74
Middle Income Group	45	72.58
Higher Income Group	06	09.68
Total	62	100

**Table 6:** Efficacy of Unani Formulations '*Qurs e Kushta Khabs al- Hadded* and *Habb e Marwareed*' on Clinical Symptoms of Sayalan al Rahim(Leucorrhea)

Clinical Symptoms		Mean $\pm$ SEM	Percentage Decrease (↓)	t-value	df	p-value
Amount of Vaginal Discharge	BT	2.56 $\pm$ 0.06	43.36	↓	13.91	<0.001
	AT	1.45 $\pm$ 0.07				
General Weakness	BT	5.03 $\pm$ 0.13	60.64	↓	18.67	<0.001
	AT	1.98 $\pm$ 0.13				
Backache	BT	5.23 $\pm$ 0.12	30.02	↓	12.29	<0.001
	AT	3.66 $\pm$ 0.16				
Anaemia	BT	1.24 $\pm$ 0.08	50.81	↓	7.82	<0.001
	AT	0.61 $\pm$ 0.08				
Excoriation	BT	0.81 $\pm$ 0.11	48.15	↓	5.50	<0.001
	AT	0.42 $\pm$ 0.07				
Ulceration	BT	0.61 $\pm$ 0.10	44.26	↓	4.80	<0.001
	AT	0.34 $\pm$ 0.06				

Paired 't' test, p<0.001 (Highly significant), p<0.05 (Significant), n=62



**Fig. 1:** Efficacy of Unani formulations '*Qurs e Kushta Khabs al- Hadded* and *Habb-e-Marwareed*' on clinical symptoms of Sayalan-al-Rahim (Leucorrhea).

**Table 7:** Effect of Unani Formulations on Hematological Parameters

Haematological parameters		Mean ± S.E.M		Percentage of Increase (↑) / Decrease (↓)		Paired 't' test	
		Base-line	After Treatment			t-value	p-value
CBC	Hb(gm/dL)	11.18 ± 0.13	11.4 ± 0.11	1.94	↑	2.15	0.035 (p<0.05)
	TLC(/mm)	6435.65 ± 164.93	6296.98 ± 172.55	2.15	↓	0.76	0.44
	N (%)	59.24 ± 0.95	58.6 ± 0.74	1.09	↓	0.57	0.54
	D L	35.5 ± 1.16	34.55 ± 0.77	2.68	↓	0.47	0.75
	C E (%)	4.32 ± 0.33	3.92 ± 0.32	9.33	↓	0.36	0.096
	M (%)	2.03 ± 0.11	1.74 ± 0.09	14.29	↓	1.99	0.051
	B (%)	0 ± 0	0 ± 0	-	-	-	-
ESR (mm)		17.9 ± 1.6	16.61 ± 1.38	7.21	↓	0.85	0.39

Statistical analysis- paired't' test; p>0.05 = Non Significant (N.S.); p<0.05 = Significant

**Table 8:** Effect of Unani Formulations on L.F.T and K.F.T. Parameters

Biochemical Parameters		Base-line Mean ± SEM	After Treatment Mean ± SEM	Percent decrease (↓) and increase (↑)		t value	p value
LFT	S.Bilirubin (mg/dl)	0.79 ± 0.03	0.76 ± 0.02	3.85	↓	1.13	0.25 p>0.05
	SGOT (IU/L)	17.46 ± 0.86	16.24 ± 0.82	7	↓	1.12	0.26 p>0.05
	SGPT (IU/L)	22.9 ± 1.75	18.9 ± 1	17.7	↓	2.4	0.019 p<0.05
	S.Alkaline Phosphatase (KA)	6.67 ± 0.31	5.96 ± 0.31	10.73	↓	2.13	0.036
KFT	S.Creatinine (mg/100 ml)	0.84 ± 0.02	0.77 ± 0.01	8.14	↓	2.88	0.005
	S.Urea (mg/dl)	24.12 ± 0.68	21.04 ± 0.59	12.75	↓	4.7	<0.001
	S.Uric Acid (mg/dL)	3.08 ± 0.11	3.24 ± 0.12	4.75	↑	1.07	0.28 p>0.05

Statistical analysis- paired't' test; p>0.05 = Non Significant (N.S.); p<0.05 = Significant

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### सारांश

#### **‘सैयलन-अल रहीम ( ल्यूकोरिया ) में कुर्स-ए-कुश्ता खब्स-अल हदीद और हब्ब-ए मरवारीद’ यूनानी औषधियों पर नैदानिक अध्ययन**

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इस अध्ययन का उद्देश्य ‘सैयलन-अल रहीम(ल्यूकोरिया) यूनानी भेषजकोशकीय मिश्रणों जैसे कुर्स-ए-कुश्ता खब्स अल-हदीद और हब्ब-ए मरवारीद’ की सुरक्षा और प्रभावकारिता का मूल्यांकन करना है। दोनों औषधियों की एक गोली चार हफ्तों तक प्रतिदिन दो बार रोगियों को मौखिक रूप से दी गई। उपचार के पश्चात रोग के नैदानिक मापदंडों जैसे योनी स्राव की मात्रा, सामान्य कमज़ोरी, पीठ दर्द, खून की कमी, खरोंच और ब्रणोत्पत्ति में क्रमशः 43.36% ( $p<0.001$ ), 60.64% ( $p<0.001$ ), 30.02% ( $p<0.001$ ), 50.81% ( $p<0.001$ ), 48.15% ( $p<0.001$ ), और 44.26% ( $p<0.001$ ), बेसलाइन की तुलना में कम कर दिया गया। अध्ययन औषधियों का कोई प्रतिकूल प्रभाव यकृत और गुर्दा क्रिया जाँच का जैव रासायनिक मापदंडों पर नहीं पाया गया। कोई प्रतिकूल प्रभाव न रोगियों द्वारा बताया गया और न ही बेसलाइन और उपचार के पश्चात् अन्वेषक द्वारा प्रयोगशाला के साथ-साथ नैदानिक जांचों में पाया गया। यूनानी मिश्रणों कुर्स-ए कुश्ता खब्स अल-हदीद और हब्ब-ए-मरवारीद को नैदानिक तौर पर सैयलन-अल-रहीम(ल्यूकोरिया) के उपचार के लिए बहुत ही प्रभावशाली एवं सुरक्षित बताया गया है।

