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# CLINICAL TRIAL TO EVALUATE THE EFFICACY & SAFETY OF UNANI FORMULATION "TAB DAMWI" IN SOO-UL-QINYA (HYPO-CHROMIC ANEMIA)

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## ABSTRACT

Hypochromic anemia due to iron deficiency is responsible for greater morbidity and mortality than any other haematologic disorder. Anaemia is a worldwide problem with the highest prevalence in developing countries. It is estimated that about 10% populations of developed countries and as much as of 25-50% in developing. National Family Health Survey discloses that 50% of Indian woman are anaemic and 20% maternal deaths is directly related to anaemia. In rural India, anemia is much more prevalent, even among men. The important etiologies may include GI blood loss due to intestinal worm infestation, NSAIDs, malignancies, multiple pregnancies, menstrual irregularities, growth spurts, etc. It is characterized by stomatitis, glossitis, swollen & inflamed gums, pallor on conjunctiva and nails, fatigue and exertional dyspnoea. The management of the disorder comprises dietary/drug supplementation containing iron in different forms. Despite availability of iron supplements, anemia is still a health challenge across the globe. The Unani drugs being safe, efficacious, easily available, cost effective and above all free from after effects of medications can play an important role in eradication of this problem if properly researched. Unani system of medicine uses holistic approach, most of the medicines employed for anemia comprise iron on one hand and having hepatoprotective/ haemopoietic activity on the other. The trial drug shows significant improvement overall in symptoms & signs and laboratory findings of the disorder as well as when compared to the standard control group. The formulation was found effective and completely safe in Soo-ul-Qinya (Hypo-Chromic Anemia).

**KEYWORDS:** Anaemia, hepatoprotective/ haemopoietic.

## INTRODUCTION

The modern equivalent of Anaemia in Unani Medicine is *Su-ul-Qinya* (an umbrella term which stands for "lack of vital treasure -blood") and it is literally translated as *Faqr-ud-Dam* (anaemia), and it is being in use profusely (Anonymous, 2012). According to Unani physicians (Ibn Sina (980-1037 AD), Ismail Jurjani (1041-1136A.D), Ibn Hubal Baghdadi (1117-1213 AD) and Hakim Azam Khan (1813-1902A.D), blood is considered to be the vital fluid of human body which is formed in the liver. Due to derangement of the liver functions and weakness of hepatic faculties or sometimes due to associated diseases, the resultant formation of blood is not normal for nourishment (*nuqs taghzia*) there by leading to anaemia with sign and symptoms such as; pallor body complexion of patient, oedematous face, eye lids and upper or lower limbs and some time generalized swelling all over the body with pitting oedema due to *raddi bukharat* (obnoxious gases), sometimes gingivitis, disturbed sleep and sometime excessive sleeping, loss of appetite, indigestion, flatulence, delayed healing of wound or ulcers (Khan HA, 2011; Sina I, 2010; Jurjani I, 2010; Baghdadi IH, 2004).

As per Unani concept anemia is due to various etiological factors; *Zof-e-jigar* (enfeeble hepatic functions), *Zof-e-meda* (gastric debility), *Azm-e-tihal* (splenomegaly), *Bawaseer* (piles), *Ahtabas-e-Tams* (amenorrhoea), Excess use of ratab wa ghaleez aghzia (moist and hardly digestible), *Dushwar Hazm aur lesdar aghzia* (spicy and oily diet) (Khan HA, 2011; Jurjani I, 2010; Sina I, 2010; Baghdadi IH, 2004;).

## MATERIAL AND METHODS

### 1. Study Drugs & Dosage

The drugs selected for the trial were Tab. Damwi, manufactured by Dawakhana Tibbia College, Aligarh Muslim University, Aligarh in the dose of 2 tab. twice daily orally in test group and Tab. Fersolate manaufactured by Glaxo co. in the dose of 1 tab. once daily orally in control group.

The composition of tablet Damvi is as follows.

**Table 1: Composition of Tab. Damvi**

| S.No. | Name of Ingredient | Scientific Name |
|---|---|---|
| 1. | Heera Kasees | Ferrous Sulphate ($FeSO_4$) |
| 2. | Zanjabeel | Zingiber officinalis |
| 3. | Revand cheeni | Rheum emodi |

**2. Study Site**

This study was conducted in the Department of Moalejat (Medicine), A&U Tibbia College & Hospital, Karol Bagh, New Delhi - 05.

**3. Study Design**

The study was designed as an open, randomized, standard controlled clinical trial. Subjects were randomly allocated to test and control groups by lottery method.

**4. Study Duration**

Two Years.

**5. Duration of Protocol Therapy**

The treatment period in test and control groups was fixed as 90 days. The patients were assessed for subjective and objective parameters starting from baseline to 30th, 60th & 90 day.

**6. Patient Selection**

Patients were screened on the basis of clinical presentation of hypo-chromic anemia, Hb% and Peripheral Blood Smear.

**7. Criteria for Selection of Patients**

Inclusion Criteria

- Patients having mild (9.1-llgm% Hb) to moderate anaemia (7.1-9 gm%).
- Patients of either sex between the age group of 18-65 years.
- Patients not taking any other drugs for 'Soo-ul-Qinya".
- Patients who are willing and able to provide informed consent.
- Patients who are willing and able to understand and follow the protocol for the duration of the study.

**Exclusion Criteria**

- Severely anemic patients(below 7gm/dcl)
- Patients below, 18 years and above 65 years of age.
- Patients enrolled in another clinical trials
- Patients having problem in complying with the study protocol
- Patients with uncontrolled hypertension.
- Patients with cardio vascular complications
- Patients with hepatic abnormality or renal disease.
- Pregnant and lactating women.
- Patients not willing to report for follow up.

**8. Laboratory Evaluation**

Investigations were carried out aiming at three important objectives of the study:

- To exclude the other patients as part of exclusion creiteria.
- To assess the objective parameters in various treatment groups.
- To establish the safety of the test drug.

Following investigations were performed before the commencement of protocol therapy for the exclusion of any concomitant acute and chronic diseases:

- Complete Blood Count- To rule out infections.
- KFT- To rule out CRF.
- Liver Function Test (LFT): S. Bilirubin, SCOT, SGPT, Alk. Phosphatase.

Following investigations were done at base line, $30^{th}$, $60^{th}$ & $90^{th}$ day (termination of therapy) for the efficacy assessment of trial drugs:

- PS-Blood
- Hb%

Following investigations were done at baseline, after $1^{st}$ week and at termination of protocol therapy for the safety assessment of trial drugs:

- Kidney Function Test (KFT): Blood Urea, S. Creatinine.
- Liver Function Test (LFT): S. Bilirubin, SGOT, SGPT, Alk. Phosphatase.
- TLC, DLC, ESR

**9. Paramaeters for the Assessment of Efficacy**

Following subjective parameters were assessed for the efficacy of the test drugs monthly:

- Pallor
- Disturbed bowel habits
- Oedema
- Disturbed appetite
- Dyspnoea
- Stomatitis and glossitis
- Dyspepsia and flatulence
- Lethargy and general weakness.

**Grading of Different Subjective Parameters**

- **Pallor Grading**

**Grade 1 Mild:** Pallor of conjunctiva and/or mucous membrane
**Grade 2 Moderate:** Above + Pallor of skin
**Grade 3 Severe:** Above + Pallor of palmar creases

- **Dyspnoea Grading**

**Grade I (minimal Dyspnea):** Dyspnea on running or on doing more than ordinary effort.
**Grade II:** on doing ordinary effort.
**Grade III (considerable Dyspnea):** on doing less than ordinary effort.
**Grade IV:** Dyspnea at rest.

- **Oedema Grading**

**Grade I:** Three is a barely detectable 2mm depression. Immediate rebound

**Grade II:** There is a 4mm deep pit and takes few seconds to rebound.
**Grade III:** There is a 6mm deep pit. 10-12 seconds to rebound.
**Grade IV:** There is an 8mm deep pit (very deep). >20 seconds to rebound.

- **Lethargy and weakness Grading**

**Grade 1:** Mild over baseline
**Grade 2:** Moderate or causing difficulty performing some ADL
**Grade 3:** Severe interfering with ADL
**Grade 4:** Disability

- **Appetite Grading**

**Grade 1:** Loss of appetite without alteration in eating habits
**Grade 2:** oral intake altered without significant weight loss and malnutrition
**Grade 3:** associated with weight loss and malnutrition
**Grade 4:** life threatening consequences

- **Dyspepsia and Flatulence Grading**

**Grade 1:** Mild
**Grade 2:** Moderate
**Grade 3:** Severe

- **Disturbed bowel habits Grading**

**Grade 1:** Mild
**Grade 2:** Moderate
**Grade 3:** Severe

- **Stomatitis and Glossitis Grading**

**Grade 1:** Mild
**Grade 2:** Moderate
**Grade 3:** Severe

Following objective parameter were used to assess the efficacy of the test drugs monthly

- Hb%

**10. Parameters for Assessment of Safety**

The safety was assessed by monitoring adverse events either volunteered by the patients or elicited by the investigator by monitoring the following investigations at baseline, after one week and at the termination of the study.

- Kidney Function Test (KFT): Blood Urea, S. Creatinine.
- Liver Function Test (LFT): S. Bilirubin, SGOT, SGPT, Alk. Phosphatase.
- TLC, DLC, ESR

**11. Withdrawal Criteria**

- Failure to consume the drug.
- Failure to report for follow up.
- Any significant adverse drug reaction or adverse event.

**12. Assessment of Temperament (Mizaj)**

Temperament of each patient was assessed on the basis of ten classical parameters (Ajnase-Ashra) as prescribed in Unani medical literature.

**13. Statistical Data Analysis**

The data was analyzed using Z-test statistical test.

## OBSERVATIONS AND RESULTS

100 subjects were screened for the study as per the screening parameters, out of which only 60 subjects fulfilled the inclusion and exclusion criteria's and were enrolled for the study. Out of 60 subjects only 40 completed the study. The baseline characteristics/demographic data of patients in the two groups are summarized in Table-2. The distribution of study subjects according to presenting symptoms is presented in Table-3. Table No.4 shows effect of Tab. Damvi and control Drug on different subjective and objective parameters before and after trial.

**Table No. 2: Baseline Characteristics/Demographic data (n=60)**

| Sl. No. | Characteristics | Treatment Group | Control Group | Percentage % |
|---|---|---|---|---|
| 1. | Total No. of Study subjects | 33 | 27 | 100 |
| 2. | Age groups (years) | | | |
| | • 18-27 | 17 | 13 | 50 |
| | • 28-37 | 9 | 8 | 28.3 |
| | • 38-47 | 4 | 3 | 11.7 |
| | • 48-57 | 3 | 2 | 8.3 |
| | • 58-65 | 0 | 1 | 1.7 |
| 3. | Sex | | | |
| | • Male | 13 | 8 | 35 |
| | • Female | 20 | 19 | 65 |
| 4. | Duration of illness (in weeks) | | | |
| | • 1-2 | 19 | 17 | 60 |
| | • 3-4 | 11 | 8 | 31.7 |
| | • 5-6 | 3 | 2 | 8.3 |

| | | | | |
|---|---|---|---|---|
| 5. | Religion | | | |
| | • Muslim | 22 | 13 | 58.3 |
| | • Hindu | 10 | 12 | 36.7 |
| | • Others | 1 | 2 | 0.5 |
| 6. | Dietary pattern | | | |
| | • Vegetarian | 11 | 14 | 41.7 |
| | • Non-Veg | 22 | 13 | 58.3 |
| 7. | Socio-economic status | | | |
| | • Low | 20 | 17 | 61.7 |
| | • Medium | 13 | 10 | 38.3 |
| | • High | 0 | 0 | 0 |
| 8. | Mizaj (Temperament) | | | |
| | • Damvi | 2 | 3 | 8.3 |
| | • Balghami | 15 | 13 | 46.7 |
| | • Safravi | 13 | 8 | 35 |
| | • Saudawi | 3 | 3 | 10 |

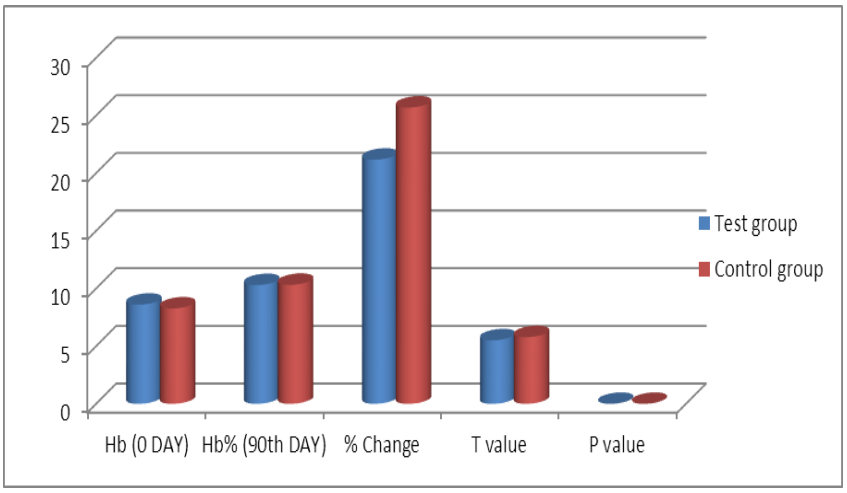
**Table No.3: Distribution of study subjects according to presenting Symptoms (N=40).**

| Group | Presenting Symptom | No. of Subjects presented with % | | | |
|---|---|---|---|---|---|
| | | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Test ($n_1$=22) | Pallor | 0 | 14 (63.6%) | 8 (36.4%) | - |
| | Edema | 0 | 4 (18.2%) | 15 (68.2%) | 3 (13.6%) |
| | Dyspnoea | 0 | 5 (22.7%) | 15 (68.2%) | 2 (9.1%) |
| | Appetite | 0 | 16 (72.7%) | 6 (27.3%) | 0 |
| | Disturbed bowel habits | 0 | 15 (68.2%) | 0 | - |
| | Lethargy & general weakness | 0 | 18 (81.8%) | 4 (18.2%) | 0 |
| | Dyspepsia | 0 | 10 (45.5%) | 0 | 0 |
| | Glossitis & Angular Stomatitis | 0 | 0 | 0 | 0 |
| Control ($n_2$=16) | Pallor | 0 | 11 (68.7%) | 5 (31.3%) | - |
| | Edema | 0 | 4 (25%) | 10 (62.5%) | 2 (12.5%) |
| | Dyspnoea | 0 | 5 (31.2%) | 11 (68.8 ) | 0 |
| | Appetite | 0 | 14 (18.7%) | 2 (12.5%) | 0 |
| | Disturbed bowel habits | 0 | 9 (56.3%) | | - |
| | Lethargy & general weakness | 0 | 11 (68.7%) | 5 (31.3%) | 0 |
| | Dyspepsia | 0 | 8 (50%) | | 0 |
| | Glossitis & Angular Stomatitis | 0 | 4 (25%) | 0 | 0 |

**Table No 4: Effects of Tab. Damvi (test drug) and Control drug on subjective and objective parameters.**

| Group | Subjective Parameters | Effect of Drug | | |
|---|---|---|---|---|
| | | $0^{th}$ Day | $90^{th}$ Day | % Change |
| Test (n=22) | Pallor | 22 | 18 | 81.8% |
| | Edema | 22 | 16 | 72.7% |
| | Dyspnoea | 22 | 13 | 59.09% |
| | Appetite | 22 | 15 | 68.1% |
| | Disturbed bowel habits | 15 | 13 | 86.6% |
| | Lethargy & general weakness | 22 | 18 | 81.8% |
| | Dyspepsia | 10 | 7 | 70% |
| | Glossitis & Angular Stomatitis | 0 | 0 | 0 |
| Control (n=16) | Pallor | 16 | 11 | 68.7% |
| | Edema | 16 | 14 | 87.5% |
| | Dyspnoea | 16 | 12 | 75% |
| | Appetite | 16 | 13 | 81.3% |
| | Disturbed bowel habits | 9 | 3 | 33.3% |
| | Lethargy & general weakness | 16 | 11 | 68.7% |
| | Dyspepsia | 8 | 4 | 50% |
| | Glossitis & Angular Stomatitis | 4 | 4 | 100% |
| Group | Objective Parameter | Effect of Drug | | |

| | | 0th Day | 90th Day | % Change | T value | P value |
|---|---|---|---|---|---|---|
| Test (n=22) | Hb (g/dl) | 8.595±0.859 | 10.300±1.085 | 21.1 7% increase | 5.5097 | 0.0001 |
| Control (n=16) | Hb (g/dl) | 8.270±0.923 | 10.320+1.288 | 25.60% increase | 5.7853 | 0.0001 |




**Safety**

During the course of the study, no adverse events were reported by the patients, no any adverse effects were detected by clinical examination and/or laboratory investigations. The formulation was well tolerated as indicated by 90% drug compliance

**DISCUSSION**

From the observations in the test group, it is evident that maximum effect was found on altered bowel habits (86.8%), followed by pallor and lethargy & weakness which were subsided in 81.8% cases, followed by edema (72.7% cases), dyspepsia (70% cases), appetite (68.1%) and dyspnoea (59.09% cases) (Table 4). The drug has maximum effect on altered bowel habits subsiding in 86.6% cases after 90 days of treatment. In the present study, increase in Hb% was found statistically extremely significant (p value <0.0001) using paired t-test in both test and control groups. While using unpaired t-test for the comparison of post study outcomes in both test and control groups, result found was not statistically significant (p value=0.9577).

Whereas, extremely significance is, the increase in hemoglobin percentage was observed in both the groups, while using paired t-test between before treatment and after treatment values. Which is indicative of that Hb% value has significantly increased after treatment in both the groups Adverse Effects: In the present study 2 (10%), 5(25%) and 2(10%) patients were reported for constipation, diarrhoea and abdominal pain respectively in control group. Whereas none of the patients in test group reported for any adverse effects. It is observed that the test drug does not have any adverse effect.

**CONCLUSION**

The aim of the study was to explore iron deficiency anemia in the light of classical Unani and modern literature to evaluate the efficacy of Unani drug on iron deficiency anemia and to provide cost effective, potent and comparatively safe drug in the management of iron deficiency anemia. Trial in both the groups (A and B) was carried out for 3 months duration. The assessment of efficacy was made, before treatment, at every month up to 3 months. A thorough clinical examination was conducted in every patient at the above-mentioned intervals Laboratory investigations were carried out before and after treatment. The parameters for the follow up study included clinical signs and symptoms such as pallor, dyspnea, edema, disturbed appetite, disturbed bowel habits, dyspepsia and flatulence, stomatitis and glossitis, lethargy and general weakness, hematological tests included Hb%,

The results were assessed for their statistical significance by using paired t-test and unpaired t-test. It was found that the test group patients had shown better response in most of the clinical sign and symptoms than control group. Statistically significant improvements were also recorded in hematological values in both groups by using paired t-test whereas, while applying unpaired t-test for post outcomes of both groups (test and control) for Hb% result was not found statistically significant. None of the patient in test group reported any adverse effect attributable to test drug. Hence, it may be concluded that the test drug is effective and safe in the management of iron deficiency anemia.

**Scope for Further Study**

The present clinical trial to evaluate the Efficacy & Safety of Unani Formulation "Tab Damwi" in Soo-ul-Qinya (Hypo-Chromic Anemia) was in itself, properly planned and executed according to the protocol. Best possible efforts were made to achieve accurate and conclusive results in the study. Nevertheless no research is complete and there is always room for further

improvement. The present study, being a time bound programme, the sample size was small (40 patients). Looking at the positive and encouraging results in the present study, it is sincerely felt, that with a larger sample size subjected to certain other sophisticated investigations, more in-depth analysis could be carried out.

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