INTERNATIONAL JOURNAL OF UNANI AND INTEGRATIVE MEDICINE

E-ISSN: 2616-4558
P-ISSN: 2616-454X
IJUIM 2021; 5(1): 43-48
Impact Factor (RJIF): 6.3
Peer Reviewed Journal
Received: 21-12-2020
Accepted: 24-01-2021

RS Verma
Regional Research Institute of Unani Medicine, Aligarh, Uttar Pradesh, India

S Parveen
Regional Research Institute of Unani Medicine, Aligarh, Uttar Pradesh, India

S Rehman
Regional Research Institute of Unani Medicine, Aligarh, Uttar Pradesh, India

R Singh
Regional Research Institute of Unani Medicine, Aligarh, Uttar Pradesh, India

S Afza
Regional Research Institute of Unani Medicine, Aligarh, Uttar Pradesh, India

J Akhtar
Central Council for Research in Unani Medicine, Jawaharlal Nehru Anusandhan Bhavan, 61-65, Institutional Area, Opp. D-Block, Janakpuri, New Delhi, India

S Ahmad
Regional Research Institute of Unani Medicine, Aligarh, Uttar Pradesh, India

AA Khan
Central Council for Research in Unani Medicine, Jawaharlal Nehru Anusandhan Bhavan, 61-65, Institutional Area, Opp. D-Block, Janakpuri, New Delhi, India

Corresponding Author:
RS Verma
Regional Research Institute of Unani Medicine, Aligarh, Uttar Pradesh, India

The efficacy and safety of a Unani compound drug *'Damavi'* in cases of anaemia: A preliminary study

RS Verma, S Parveen, S Rehman, R Singh, S Afza, J Akhtar, S Ahmad and AA Khan

Abstract
Anaemia is an urgent public health burden in India. Available synthetic medicines have serious side effects, therefore, medicines of herbal origin have been extensively used in therapeutic management of anaemia for a long time. The present study aims to evaluate the efficacy and safety of Unani compound drug *damavi* in cases of anaemia (*Soo-ul-qiniya*). The data presented in this work is a part of a multicentric, open level clinical study conducted on 102 anaemia cases at Regional Research Institute of Unani Medicine, Aligarh, during 2015-2018. The statistical analysis of data presented was done by using one-way analysis of variance (ANOVA) followed by Dennett's' test and, p value of ≤0.05 was considered significant. In symptomatic studies a significant reduction in pallor, weakness, fatigue and dyspnoea respectively has been observed, when compared with the values of 1st -day and different follow-up of treatments. In haematological studies a significant increase in the level of haemoglobin, red blood corpuscles (RBC), packed cell volume (PCV) were observed. In biochemical studies, no significant changes were observed in liver function test and kidney function test. Therefore, it was concluded that Unani compound drug *damavi* is haematinic and is also safe for both liver and kidney functions and can be used in the patients of anaemia safely.

Keywords: Anaemia, unani drug *damavi*, haematinic, packed cell volume, *Soo-ul-qiniya*

Introduction
Anaemia is one of the most familiar nutritional disease worldwide and is common in adolescent girls due to increased growth and menstrual blood loss. According to World Health Organization (WHO), there are two billion people with anaemia in the world and half of the anaemia is due to iron deficit [1]. WHO estimates that anaemia prevalence among adolescent girls is 27% in developing countries and 6% in developed countries [2]. The prevalence of anaemia in pregnant and non pregnant females aged 15-49 years is 50.3% and 53.1% respectively in India [3, 4].

Anaemia due to lack of iron is maintained by iron supplements and a diet of food rich in iron. In modern medicine system many drugs such as folate, vitamin B12 and iron tablets have been therapeutically used for management of anaemia. Iron pills are taken together with vitamin C to enhance iron absorption. Iron tablets may have certain side effects such as abdominal cramping, nausea, constipation, and dark, hard stool [5]. Now, attention is focused on herbal drugs including Unani drugs due to their variable role in anaemia with no or negligible side effects and cost effectiveness. Therefore, there is an urgent need to search for effective and safe drugs for therapeutic management of anaemia. Hence, the present study was undertaken to evaluate the safety and efficacy of Unani compound drug *damavi* on 102 patients.

In Unani system of medicine, there is decrease in the amount of blood and alteration in its constituents with decrease in the number of Red Blood Cell (*kuiyat-e-hamrah*) and severe malfunction of the liver due to alteration in its temperaments in anaemia [6-11].

In Unani System of Medicine many *Mufrad dawa* (single drugs), namely, Zafran (*Crocus sativus* L.), Maweez Munaqqa (*Vitis vinifera Linn*), Darchini (*Cinnamomum zeylanicum* L.), Sadkofi (*Cyperus rotundus* L.), Asaroon (*Asarum europaeum* L.), Balchhar (*Nardostachys jatamansi D. Don.*), Halela (*Terminalia chebula* Retz.), Balela (*Terminalia belerica* Gaertn.), as well as *Murkkab dawa* (Compound drugs): *Majoon-e-Dabeed-ul-Ward*, *Majoon Khabsul Hadeed*, *Jawarish Amla*, *Sharbat-e-Faulad*, *Sharbat-e-Maweez* had been used in past for management of anaemia [12, 13]. Thus, in the present study the efficacy of *Damavi* was studied in patients of anaemia, since the ingredients of this drug have been reported to improve the *faqr-ud-Dam* (anaemia) activity [13].

Materials and Methods

Study design

Multicentric, randomized and open level clinical study. Unani formulation *Damavi* was allotted for investigation by Central Council for Research in Unani Medicine, New Delhi and the study was carried out at Regional Research Institute of Unani Medicine (RRIUM), Aligarh from 2015 to 2018. One hundred two (102) patients, aged 18-65 years of either sex were selected from the lot of patients attending the Out Patient Department (OPD) of the institute following the predesigned inclusive/exclusive criteria. A total 454 patients visiting OPD of the institute were screened and 175 were registered for the present study. Of these 102 completed the preliminary clinical trial and 72 were dropped out. The efficacy and safety of Unani pharmacopoeial drug *Damavi* was evaluated on the basis of demographical, symptomatical, haematological and biochemical parameters. The patients were be assessed clinically at every 2 weeks, i.e., at days 0, 14, 28, 42 and 56, days. All patients were included in the study after obtaining written informed consent from Institutional Ethics Committee (IEC). This project is registered in Clinical Trials Registry-India (CTRI/2015/10/006273).

Selection criteria

Patients were enrolled on the basis of following inclusion and exclusion criteria:

Inclusion Criteria

Patients in the age group of 18-65 year of either sex having the signs and symptoms of anaemia. Haemoglobin in the range of 8.0-12.0 gm% in males and 8.0- 10 gm% in females. Whitish or yellowish complexion of face and skin. Patients with or without any of the following signs and symptoms viz; pallor, weakness, fatigue and dyspnoea.

Exclusion Criteria

Patients with haemoglobin less than 8.0 gm%, history of acute blood loss, chronic diseases requiring long term treatment, pregnant and lactating women were excluded.

Drug, dose and mode of administration

Unani compound drug *damavi* was given in the dose of 2 tablets (250 mg each) orally to the patients twice a day after meal for a period of 56-days. The haematological and biochemical investigation were conducted on day one and at the end of the study i.e. 56th day.

Criteria for assessment of efficacy

To assess the response of treatment in patients of anaemia (*Soo-ul-qiniya*), the following parameters were used.

1. Subjective parameters

A. Symptomatic studies

- Pallor
- Weakness
- Fatigue
- Dyspnoea

Grading of different subjective parameters

Pallor

- Grade 0= No paleness
- Grade 1= Mild paleness in conjunctiva.
- Grade 2= Paleness in conjunctiva, tongue and nail beds.
- Grade 3= Marked paleness on patient's face and palmar creases

Weakness

- Grade 0= No weakness
- Grade 1= Weakness on heavy work or excessive play.
- Grade 2= Weakness on routine work or normal play.
- Grade 3= Weakness even on rest.

Fatigue

- Grade 0= No fatigue or fatigue only after excessive work or play.
- Grade 1= Fatigue on doing less than accustomed work or play.
- Grade 2= Fatigue on doing routine work or after normal play.
- Grade 3= Fatigue even on rest.

Dyspnoea

- Grade 0= No dyspnoea or dyspnoea with more than ordinary physical activity.
- Grade 1= Dyspnoea with ordinary physical activity.
- Grade 2= Dyspnoea with less than ordinary physical activity.
- Grade 3= Dyspnoea on rest.

B. Demographic studies

C. Assessment of safety studies

i. Biochemical analysis

Serum glutamate oxaloacetate transaminase (SGOT, E.C. 2.6.1.1.) and serum glutamate pyruvate transaminase (SGPT, E.C. 2.6.1.2) were done by the method described by International Federation of Clinical Chemistry (IFCC) [13], serum alkaline phosphatase enzyme (S-ALP, EC. 3.1.3.1)) by the method of Wilkinson *et al* (1969) [14], blood urea by the method of Tiffany *et al.* (1972) [15], serum creatinine by Bowers (1980) method [16], serum uric acid by modified Trinder peroxidase Method [17], serum bilirubin by modified method of Pearlman & Lee (1974) [18].

ii. Haematological analysis

Haematological parameters were done according to the method described by Mukherjee (1990) [19]. These included haemoglobin (Hb), erythrocyte sedimentation rate (ESR), total leucocytes counts (TLC), red blood corpuscles (RBC), platelet counts and differential leucocytes counts (DLC): polymorphs, lymphocytes and eosinophil counts, packed cell volume (PCV), mean cell volume (MCV), mean cell haemoglobin concentration (MCHC), and mean cell haemoglobin (MCH) and platelets counts.

Collection of blood serum

Blood samples were collected by puncturing the vein at each investigation. 1.0 ml of blood with ethylene diamine tetra acetic acid (EDTA) was used for various haematological parameters and another 2.0-2.5 ml of blood sample was allowed to clot and serum was separated by centrifugation, which was used for various biochemical parameters.

Statistical analysis

Data were analyzed statistically by one-way analysis of variance (ANOVA) followed by Dennett's' test. The values were considered significant when the P-value was found less than 0.05. The findings were tabulated and compared statistically.

Results and discussion

Demographic Studies

Out of 102 patients of anaemia (*Soo-ul-qiniya*), 01(1.0%) were male and 101 (99.02%) female, which shows that female have higher incidence of anaemia as compared to male. Similar observations had been reported by earlier workers [20]. 18-27 years (mean age 20.79 years) age group of female is more susceptible to anaemia (table-2)**.** The duration of the disease observed in 89 (87.25%) female is 1-6 month. Non-vegetarian 89 (87.26 %) patients had more incidences than vegetarian 13 (12.75%) (table-3). Similar findings were reported by earlier researchers [21]. Lower income group had more incidence of anaemia 62 (60.78%) than higher income group 24 (23.53%) followed by middle income group 16 (15.68%) (table-3). Similar inference had been reported by other workers [21]. House wife had more incidence 59 (57.84%) than students 23 (22.55%) followed by others 19 (18.63%) and businessman 02 (1.96 %). Similar results were reported by earlier [22]. Patient of moderate nature of work had more incidence 93 (91.18%) than sedentary 07 (6.86%) followed by strenuous type of work 02 (1.96%). Normal appetite patients 56 (54.90%) had more incidence than abnormal 46 (45.1%). Patient of regular bowel 68 (66.67%) had more incidence than constipation 18 (17.65%) followed by Irregular bowel 16 (15.69%). Distribution of patients according to temperament showed that a maximum number of patients in safrawi *(bilious)* 91 (89.22%) followed by balghami (phlegmatic) patients 07 (6.86%) and *damavi* (sanguine) 04 (3.92%) (table-3). Similar results were reported by other workers [23].

Subjective Parameters

Symptomatic Studies

When Unani compound drug *damavi was* given to the patients orally 2-tablet (250 mg each) once a day after meal for 56-days. A significant reduction in symptoms pallor, weakness, fatigue and dyspnoea 20.0 % (P<0.001) on 28th-days, 25.81 % (P<0.0001) on 42th-days and 53.55 % (P<0.0001) 56th-days, 14.69 % (P<0.01) on 28th-days, 25.42% (P<0.0001) 42th-days and 53.67% (P<0.0001) on 56th-days, 14.05% (P<0.001) on 28th-days, 25.28% (P<0.0001) on 42th-days and 53.93% (P<0.0001) 56th-days, 19.05% (P<0.001) on 28th-days, 30.95% (P<0.0001) 42th-days and 54.76% (P<0.0001) 56th-days respectively, had been observed, when compared with the values of baseline and different follow-up of treatment (56th-days) (Table-4 and fig-1). Similar findings had been reported by other researchers [24].

Objective parameters

Assessment of safety

i. Biochemical studies

Effect on liver and kidney function tests

Biochemical studies undertaken have indicated that there were no significant changes in liver function tests as well as kidney function tests. Therefore, it can be inferred that the test drug damavi did not induce any negative or unfavorable response. The safety of the drug is therefore conformed (Table-7).

ii. Haematological studies

Unani compound drug *damavi* significantly increased the level of haemoglobin by 6.54% ((P<0.001), Red blood corpuscles (RBC) by 8.02% (P<0.001) (Table-5), Packed Cell Volume (PCV) by 7.5% (P<0.001) (Table-5, 6 and fig-2), when compared with the values of baseline (1st-day) and post treatment (56-days). The findings of haematological study clearly indicated that increased level of RBCs, Hb, PCV suggest that Unani compound drug *damavi* helped in improving the anaemia (*Soo-ul-qiniya*).Similar findings had also been reported by other workers [25].

Conclusion

In the light of the findings and the observations, it can be concluded that Unani pharmacopoeial drug *Damavi* significantly improves anaemia and possesses significant haematinic effect. Significant reduction in various anaemia symptoms had also been observed. Besides, the drug investigated is safe and did not induce any toxic effect, particularly on liver and kidney functions. Further studies are warranted in a large group for better understanding of the efficacy and safety of the drug damavi.

Table 1: Composition of *Damavi* [26]

Name of ingredient	Scientific name	Quantity
Rewand Chini	*Rheum officinale* Baill	500 g
Hira Kasees	Ferrous Sulphate (FeSO4)	500 g
Zanjabeel	*Zingiber officinalis* Rosc.	500 g
Samagh-e-Arabi	*Acacia nilotica* (L.) Delile.	250 g

Table 2: Demographic age-wise data of anaemia patients.

Variable	Number of females and %	Mean age of females
1. Age group (in years)		
18-27	47 (46.08%)	20.79± 3.28
28-37	34 (33.33%)	32.5 ± 2.82
38-47	20 (19.61%)	43.55 ± 6.05

[Data represent ± SD of 102 set of observation.]

Table 3: Demographic data of anaemia patients.

Variables	Number of females and %
2. Chronicity of disease i. 1- 6-Months	88 (88.28%)
ii. 7-Months-1Year	11(10.78%)
iii. 2-4 Years	03 (2.94)
3. Socio-economic status i. High income group	10 (9.8%)
ii. Middle income group	28 (27.45%)
iii. Lower income group	64 (62.74%)
4. Dietary habits i. Vegetarian	13 (12.75%)
ii. Non-Vegetarian	89 (87.26%)
5. Occupational status i. Housewife	59 (57.84%)
ii. Bussiness	02 (1.96%)
iii. Student	28 (27.45%)
iv. Others	12 (11.77%)
6. Nature of work i. Sedentary	07 (6.86%)

ii. Moderate	93 (91.18%)
iii. Strenuous	02 (1.96%)
7. Nature of appetite i. Normal	56 (54.90%)
ii. Abnormal	46(45.1%)
8. Nature of bowel i. Regular	67(65.69%)
ii. Irregular	18 (17.65%)
iii. Consipation	18 (17.65%)
9. Type of temperament i. Bilious (safrawi)	91 (89.22%)
ii. Phlegmatic (balghami)	07 (6.86%)
iii. Sanguine (damavi)	04 (3.92%)
iv. Melancholic (saudawi)	Nil

[Data represent ± SD of 102 set of observation.]

Table 4: Effect of Unani compound drug damavi on symptoms in anaemia patients.

Treatment → / Symptom ↓	Baseline (1st -Day)	1st F-up (14-days)	2nd F-up (28- days)	3rd F-up (42- days)	4rth F-up (56-days)
1. Pallor	1.55 ± 0.74	1.5 ± 0.77•	1.24 ± 0.85***	1.15 ± 0.86***	0.72 ± 0.84***
2. Weakness	1.77 ± 0.55	1.62± 0.65•	1.51 ± 0.67*	1.32 ± 0.79***	0.82 ± 0.80***
3. Fatigue	1.78 ± 0.46	1.71± 0.56•	1.53 ±0.64***	1.33 ± 0.78***	0.82 ± 0.81***
4. Dyspnoea	1.68 ± 0.58	1.65± 0.64•	1.36 ± 0.79**	1.16 ± 0.87***	0.76 ± 0.83***

[*P<0.05, **P<0.01 are significant, ***P<0.001 is highly significant and •P is not significant]
Dennett's' test was used between base line (1st-day) and post-treatment (PT) (56-days) group.
Grading of different symptoms such as pallor, weakness, fatigue and dyspnoea are 0, 1, 2, 3.

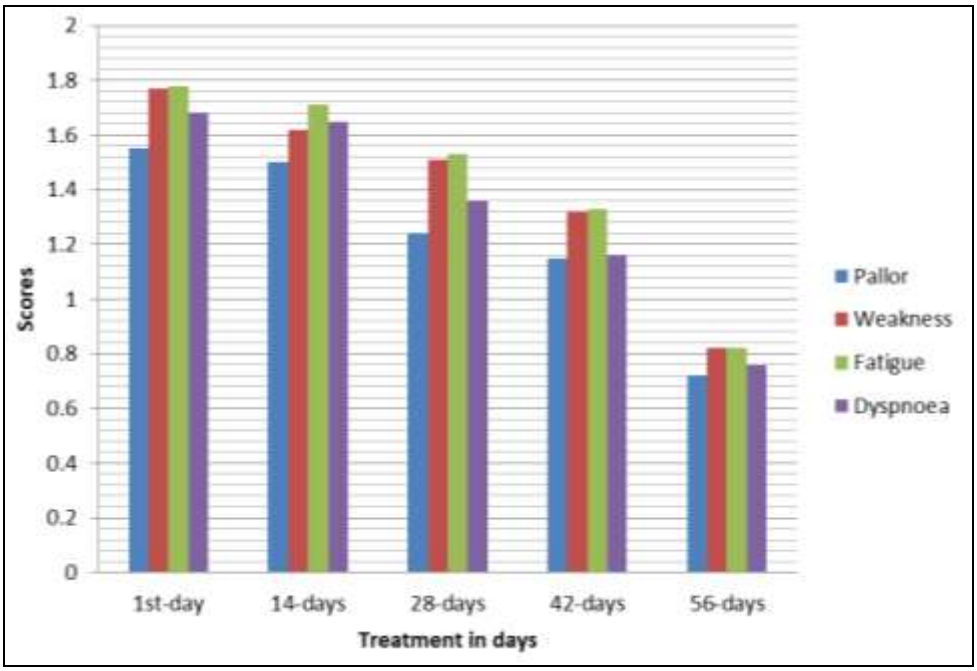

Fig 1: Effect of Unani compound drug damavi on symptoms in anaemia patients.

Table 5: Effect of Unani compound drug *damavi* in the levels of haemoglobin, R.B.C. count, total leucocyte counts (T.L.C.), erythrocyte sedimentation rate (E.S.R.), platelets counts, polymorph, lymphocyte and eosinophil counts in anaemia (*Soo-ul-qiniya*) patients.

Parameter → / Group ↓	Haemoglobin (gm %)	R.B.C. (10^6 /mm^3)	T.L.C. (10^3/mm^3)	E.S.R. (mm /hr)	Platelet Counts (Lac/ mm^3)	Differential leucocyte counts (DLC)		
						Polymorphs (%)	Lymphocytes (%)	Eosinophils (%)
Baseline (1st -day)	10.10 ± 0.33	3.49 ± 0.89	7.22 ± 2.07	41.0 ± 14.37	2.50 ± 0.82	66.00 ± 9.61	29.0 ± 9.65	5.0 ± 1.97
Post- treatment (56th -days)	10.76 ± 0.95***	3.77 ±0.45***	6.68 ± 1.99•	41.0 ±12.14•	2.30 ± 0.73•	66.00 ±9.48•	29.00 ± 9.55•	5.0 ± 2.21•

[***(P<0.001) highly significant and •P is not significant]
Data represent ± SD of 102 patients. For statistical significance one-way analysis of variance (ANOVA) followed by Dennett's' test was used between base line (1st-day) and post-treatment (56-days) group.

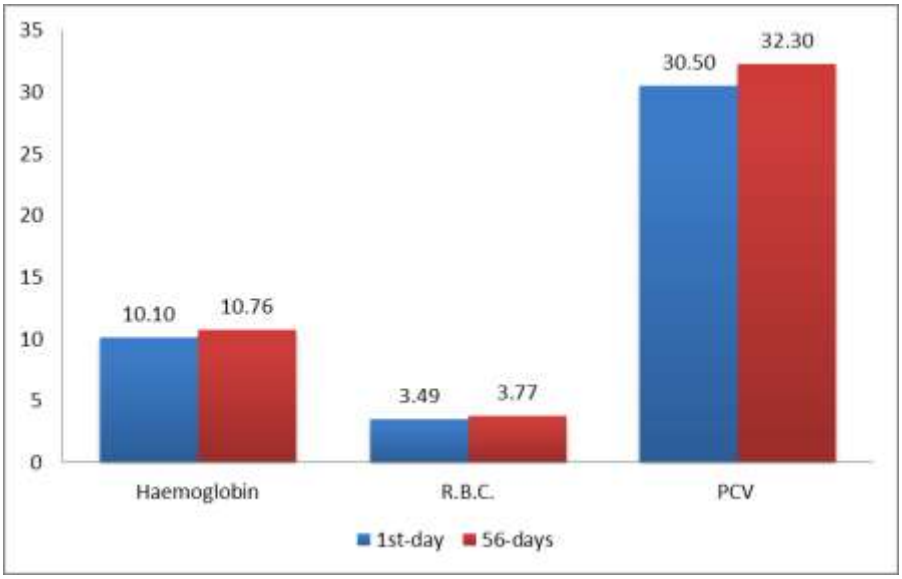

Fig 2: Effect of Unani compound drug *damavi* in the levels of haemoglobin, R.B.C. counts, and packed cell volume (PCV) in anaemia patients.

Table 6: Effect of Unani coded drug *damavi* in the level of packed cell volume (PCV), mean cell volume (MCV), mean cell haemoglobin (MCH) and mean cell haemoglobin concentration (MCHC) in anaemia (*Soo-ul-qiniya*) patients.

Parameter→ / Group↓	PCV (%)	MCV (μ^3)	MCHC (g/dl)	MCH (pg)
Baseline (1st -day)	30.05 ± 2.81	87.0 ± 6.43	32.83 ± 2.09	30.12 ± 3.04
Post- treatment (56th -days)	32.3 ± 3.14***	86.34 ± 6.77˙	32.63 ± 0.21˙	29.38 ± 2.79˙

[***(P<0.001) highly significant and ˙P is not significant]
Data represent ± SD of 102 set of observation. For statistical significance one-way analysis of variance (ANOVA) followed by Dennett's' test was used between base line (1st-day) and post-treatment (56-days) group.

Table 7: Effect of Unani compound drug *damavi* in the levels of SGPT, SGOT, serum alkaline phosphatase, serum bilirubin blood urea, serum creatinine and serum uric acid in anaemia (*Soo-ul-qiniya*) patients.

Parameter→ / Group↓	SGOT (IU/L)	SGPT (IU/L)	Alkaline Phosphatase (IU/L)	Bilirubin (mg %)	Blood Urea (mg %)	Creatinine (mg %)	Uric Acid (mg %)
Baseline (1st -day)	20.81 ± 13.82	23.33 ± 14.57	73.46 ± 22.56	0.78 ± 0.56	21.28 ± 6.32	0.83 ± 0.14	0.78 ± 0.56
Post- treatment (56th -days)	20.8 ± 9.45˙	23.27 ± 1.51˙	71.62 ± 22.3˙	0.79 ± 0.69˙	20.53 ± 7.53˙	0.85 ± 0.20˙	0.79 ± 0.69˙

[˙P is not significant]
Data represent ± SD of 102 set of observation. For statistical significance one-way analysis of variance (ANOVA) followed by Dennett's' test was used between base line (1st-day) and post-treatment (56-days) group.

Acknowledgement
The authors are indebted to Central Council for Research in Unani Medicine (CCRUM), New Delhi, for financial support. We also thank Mr Kushal Pal Singh, Mr Javed Akthar, Mr Mohd Akbar Rais and Mr Tariq Ali Beg Lab Technicians and Mr Shish Mohammad, Lab Attendant of Biochemistry and Pathology Laboratory, RRIUM, Aligarh, for help in various investigations.

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