

FINAL REPORT

VII (d)

ON

**CLINICAL, HAEMATOLOGICAL, BIOCHEMICAL, AND
IMMUNOLOGICAL STUDIES ON PATIENTS OF
CHRONIC ARSENIC TOXICITY AND ITS
HOMOEOPATHIC MANAGEMENT**

By

NATIONAL INSTITUTE OF HOMOEOPATHY

Block-GE, Sector-III, Salt Lake

Calcutta - 700 0106

JULY 2003



**FINAL REPORT OF RESEARCH PROJECT SANCTIONED UNDER THE SCHEME FOR
EXTRA MURAL RESEARCH IN ISM&H**

1. **Title of the project:** Clinical, Haematological, Biochemical And Immunological Studies on Patients of Chronic Arsenic Toxicity and It's Homoeopathic Management
2. **Principal Investigation & Co-Investigators:** Dr. Asok Kumar Das
3. **Implementing Institutions & other collaborating Institutes :**

National Institute of Homoeopathy, Block – GE,
Sector – III, Salt Lake, Kolkata – 700 106

Other collaborating institutes :

- School of Tropical Medicine, Govt. of West Bengal: The Dept. of Chemistry, School of Tropical Medicine to estimate arsenic in water and other biological samples.
- Defence Institute of Physiology and Allied Science, New Delhi as per the instruction of the Secretary, Dept. of ISM & H to study the homocysteine level in the blood of patients of chronic arsenic toxicity (CAT)
- Bose Institute, Kolkata for immunological study of patients of CAT.

4. **Date of commencement :** 01.01.1999


5. **Duration :** Over 2 yrs.

6. **Date of completion :** 26.07.03

7. **Objectives as approved :**

The aims of the study were to examine the nature and degree of arsenic toxicity in the population exposed through drinking water and to suggest remedial measures, if any. The objectives of the studies were as follows:

- A] To study the clinical features of those persons who have the history of drinking arsenic contaminated tubewell water for a long time.
- B] To study the haematological parameters of patients of chronic arsenic toxicity.
- C] To study the function of liver of affected persons through enzyme study.
- D] To study the lipid profile of affected persons.

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- E] To study the function of kidney by estimation of blood urea and creatinine.
- F] To study the function of cardiovascular system by ECG and other methods.
- G] To estimate the different Immunoglobulins like IgG, IgD, IgM, IgA and IgE in patient's serum.
- H] To study the function of lymphocytes and macrophage cells of affected individuals.
- I] To estimate arsenic deposited in nails, hairs and skin scales of affected persons.
- J] To estimate the amount of arsenic in urine excreted by the patients.
- K] To estimate the amount of arsenic present in tubewell water consumed by the patients in limited number in the project area.

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The documentation of the efficacy of Homoeopathy in the treatment of cases of chronic arsenic toxicity and the discovery of presence of homocysteine in the urine of patients of chronic arsenic toxicity are the two original contributions of the present study

i) **List of research publication with complete details:**

Authors, Title of paper, Name of Journal, Vol., Page, Year.

- "Homocystinuria in patients of chronic arsenic toxicity due to prolonged drinking of arsenic contaminated sub-soil water" – communicated to one of the most prestigious international online Journal "Environmental Health Perspectives", USA for publication.
- "Studies on cases of chronic arsenic toxicity and its implication in the development of Homoeopathic Materia Medica and Repertory" – communicated to The Editor, Dr. Peter Fisher, Homoeopathy, UK for publication.
- "Chronic Arsenicosis: Epidemiological study, Investigation and Homoeopathic Management" published in the proceeding of the Workshop on Arsenic Hazards in Ground Water of West Bengal – Steps for Ultimate Solution organized by Central Ground Water Board, Government of India in collaboration with Public Health Engineering Department, Govt. of W.B., Water Investigation Development Directorate, Govt. of W.B. held on 7th February, 2002.
- Evaluation of efficacy of individualized homoeopathic treatment in cases of chronic arsenic toxicity through drinking arsenic contaminated sub-soil water (under preparation).

ii) **Manpower trained on the project:**

a) **Research Associates or Research Fellows:**

1. Dr. Mohan Giri
2. Dr. Snigdha Chottopadhyay
3. Dr. Arup Kumar Pal .

b) **Other Technical Personnel trained:**

1. Chandrashila Jadav
2. Manabendra Baur
3. Prabir Kumar Shao

iii) **Patents taken, if any:** The finding of homocystinuria in a patient of chronic arsenic toxicity is first reported in the present study in the world, hence may be patented. Further work is necessary in establishing its mechanism and possible use in mitigating the toxicological effects.



iv) Products developed, if any: Nil

13. Abstracts (300 words for possible publication in the newsletter of the Department of ISM&H).

Arsenic level in ground water beyond the maximum permissible limit of 0.01mg/litre has been found to occur within the shallow aquifer in the interfluvial region of Bhagirathi-Hoogly and Jalangi-Ichamati rivers spread over to 65 blocks in 8 districts of West Bengal and adjoining western, southern and northern part of Padma in Bangladesh. The source of arsenic in ground water is natural. Dissolution and desorption of arsenic from arsenic rich iron oxyhydroxide present in the soil grain appear to be the main mechanism of ground water contamination. Such presence of arsenic in drinking water in excess of acceptable limit has become a major health concern in West Bengal and Bangladesh, as rural water supply is mostly dependent on these shallow tube wells. According to the study of Central Ground Water Board, eastern region, Kolkata eight districts of West Bengal state with 65 administrative blocks have shown arsenic manifestations where five million people were in the zone of risk.

Despite the magnitude of this potentially, there is no effective therapy of chronic arsenic toxicity. Since homoeopathic treatment is not based on the name of the disease, an attempt had undertaken to evaluate the efficacy of homoeopathy in the treatment of these cases through single blind placebo controlled clinical study. Moreover clinical, haematological, biochemical, studies on these group of patients were also included in this study.

It was observed that out of 5340 persons studied in the two districts of West Bengal (North 24 parganas and Malda) 386 (7.23 %) individuals were affected with arsenicosis. Irrespective of sex, arsenicosis cases were more common in the age group between 21-50 years.

The subjects had consumed drinking water containing arsenic 500- 1050 mcg/L for 2 to 10 years and had three major skin manifestations: hypopigmentation, hyperpigmentation and keratosis of the palms or soles. Out of 361 patients of chronic arsenic toxicity studied, 93.07% of patients showed skin symptoms, 56.51% of respiratory symptoms, 45.15% of gastrointestinal symptoms, 11.08% of cardiovascular symptoms, 24.65% of nervous system, 1.39% of malignancy and 56.23 % of general symptoms. The most significant finding of biochemical studies was presence of homocysteine in the urine of 95 % patients, but none of the controls. This will open a new area of research in the field of arsenic toxicity regarding its mechanism as well as possible remedy through dietary measures, which may again be integrated with homoeopathic treatment. Liver function profiles were unchanged except an increased serum globulin in the arsenic patients, thus indicating the possible involvement of immunological system in chronic arsenicosis.

A total of 216 cases of CAT were treated with individually selected homoeopathic medicines for 6 to 24 months and 145 cases of arsenicosis cases were given placebo as controls. The patients of both the groups were advised to drink safe water. These study subjects were treated & fully observed for 6 to 24 months. Clinical scoring of patients of both experimental and placebo groups were done before and after treatment. The change of clinical scoring before and after homoeopathic constitutional treatment is statistically significant in comparison to the control group, and thus proving the efficacy of homoeopathic treatment in cases of chronic arsenic toxicity. Sulphur, Arsenicum album and Hepar sulph are the three commonly indicated medicines in these cases.

The presence of homocysteine in the urine of the patients of chronic arsenic toxicity is a highly original, potentially significant observation of this study that promises new insight into arsenic toxicity. The exacerbation of



arsenicosis by nutritional deficiency has long been postulated, but never proved. This linkage of homocystinuria with arsenicism offers both a mechanism and, possibly, a remedy — a significant contribution of homoeopathy in the field in medical science.

14. Budget approved/expenditure incurred (head-wise).

(a) **Total amount sanctioned for the project:** Rs. 14.04 lakhs + Rs. 4.8 lakhs = 18.84 lakhs (vide letter No. Z – 31012/7/98 – Y&N dt. 10.01.2000)

(b) **Amount released by the Ministry so far:** Rs. 16.00 lakhs.

(c) **Amount utilized by the Institution so far (Upto 31.3.2003) :** Rs. 12.36 lakhs.

(d) Breaks-ups of Amount utilized:

- (i) Salary: Rs. 4.50 lakhs
- (ii) Equipment: Rs. 4.82 lakhs
- (iii) Other items: Rs. 3.04 lakhs

Total: Rs. 12.36 lakhs

(Name & signature of Principal Investigator with date)



Plate-A, 2nd Floor,
Office Block-III, NBCC Complex,
East Kidwai Nagar, ND-23
Dated: 23rd July, 2020

To

The Pay & Accounts Officer (Sectt.),
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi.

Sub: - Release of Grants-in-aid of Rs.7,24,680/- as 1st installment for SARS CoV-2 infection and COVID 19 disease under Modified Extra Mural Research (EMR) Scheme during 2020-21-reg.

Sir,

In exercise to powers delegated under DFPR-1978, I am directed to convey the sanction of the President of India for release of an amount of **Rs.7,24,680/- (Rupees Seven Lakhs Twenty-Four Thousand Six Hundred & Eighty Only)** to "National Institute of Homoeopathy, Salt lake, Kolkata" as 1st installment of recurring grants for the Research Project titled "A community-based cluster randomized open level controlled field trial to evaluate the effectiveness of Homoeopathic Prophylaxis & standard prophylaxis against COVID-19" under EMR Scheme during the year 2020-21.

2. The Sanction has been issued as per Rules 228 to 245 of General Financial Rules – 2017. The grant-in-aid will be subject to the conditions and provisions of the modified EMR Scheme for SARS CoV-2 infection and COVID 19 disease and no amount or part thereof shall be delivered/utilized to any other purpose than the one for which it has been sanctioned.

3. The accounts of the grantee institution/organization shall be open to inspection by the sanctioning authority and audit both by the CAG of India under the provisions of CAG (DPC) Act, 1971 and internal audit wing of the O/o CCA of the Ministry, whenever the institution or organization is called upon to do so.

4. The Grants-in-aid of **Rs.7,24,680/- (Rupees Seven Lakhs Twenty-Four Thousand Six Hundred & Eighty Only)** is a recurring grants.


5. This sanction is subject to condition that the grantee institute will disburse this grant-in-aid through EAT (Expenditure, Advance and Transfer) Module of PFMS as per the guidelines under Ministry of Finance.

6. The sanction is issued subject to conditions that information/details in respect of Direct Benefit Transfer (DBT) under the budget heads Salary/Manpower and TA/DA as per notification of the Scheme under Section 7/57 of Aadhaar Act 2016 will be provided/uploaded to this Ministry on monthly basis as per DBT App/Format by the Principal Investigator/Organization.

7. The expenditure is debitable to the Demand No. 4- Ministry of AYUSH, 2210-Medical and Public Health (Major Head), 2200-Other System (Minor Head), 07-Grants for Extra Mural Research Projects through Research Institute (Pvt./Semi-Govt./University/NGO's etc.), 070031-Grants-in-aid (General) during 2020-21. Scheme Code (3121-EMR).

8. No Utilization Certificate is pending against this institute during previous years under this scheme.

9. This issues with the approval of the IFD concurrence Dy. No. C- 169 dated 20.07.2020.


कुन्दन भा. सिन्हा/KUNDAN B. SINHA
अवर सचिव/Under Secretary
आयुष मंत्रालय, भारत सरकार
Ministry of AYUSH, Government of India
आयुष भवन, बी-ब्लॉक, गुप्त लु.
AYUSH Bhawan B-Block, GPU L.

Contd.....2/-

Yours faithfully,



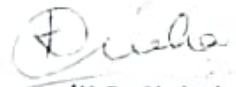
(K.B. Sinha)

Under Secretary to the Govt. of India

Copy forwarded for information and necessary action to:

1. The Director General of Audit, Central Revenues, I.P. Estate, New Delhi-110002.
2. Niti Aayog, (Health Division), Sansad Marg, New Delhi.
3. Cash (AYUSH) Section for preparing bill.
4. DDG (P&E), Ministry of AYUSH, New Delhi.
5. Sanction Register.
6. The Director, National Institute of Homoeopathy, Salt Lake, Kolkata with the request that the above released grants should mandatorily be disbursed only through EAT (Expenditure, Advance and Transfer) Module of PFMS as per the guidelines under Ministry of Finance.
7. Dr. Subhash Singh, Director, NIH, Kolkata.

कुन्दन भा. सिन्हा/KUNDAN B. SINHA
अवर सचिव/Under Secretary
आयुष मंत्रालय, भारत सरकार
Ministry of AYUSH Govt. of India
आयुष भवन, बी-ब्लॉक, प्रोटीजे कॉम्प्लेक्स, आई.एन.ए. नई दिल्ली
AYUSH Bhawan B-Block, GPO Complex INA, New Delhi.



(K.B. Sinha)

Under Secretary to the Govt. of India

N.B.

The Institute will submit/maintain the following documents in connection with the above grants: -

1. Utilization Certificate as per the provision of Scheme Guidelines & as per prescribed format of GFR-2017 (i.e. GFR-12-A).
2. Audited Statement of Expenditure indicating accrued interest, if any, on the released grants.
3. Detailed Research Project Report against the released grants.
4. The Head of the Institute shall be personally accountable for proper utilization of the grants.
5. The details of approved budget for the above project are as under: -

Heads	Total	1st installment	10 % withheld amount
Salary for ONE SRF @ 35,000+HRA for 3 months	Rs. 1,30,200/-	Rs. 1,30,200/-	-
Medicines	Rs. 75,000/-	Rs. 75,000/-	-
Books	Rs. 10,000/-	Rs. 10,000/-	-
IR Thermal Gun	Rs. 20,000/-	Rs. 20,000/-	-
Report Writing	Rs. 5,000/-	Rs. 5,000/-	-
PPE Kit	Rs. 60,000/-	Rs. 60,000/-	-
Sterilium	Rs. 10,000/-	Rs. 10,000/-	-
Surgical Mask 3ply	Rs. 20,000/-	Rs. 20,000/-	-
Sanitizer, Hand Rub, Surgical Gloves	Rs. 25,000/-	Rs. 25,000/-	-
Printing of forms and questionnaires	Rs. 40,000/-	Rs. 40,000/-	-
TA/DA	Rs. 2,25,000/-	Rs. 1,91,000/-	Rs. 34,000/-
Stationary, Postage & Photocopy	Rs. 65,000/-	Rs. 65,000/-	-
Monitoring/Audit	Rs. 15,000/-	Rs. 15,000/-	-
Contingency	Rs. 45,000/-	Rs. 35,000/-	Rs. 10,000/-
Data Analysis	Rs. 30,000/-	Rs. 20,480/-	Rs. 9,520/-
Publication of Research outcome	Rs. 5,000/-	Rs. 3,000/-	Rs. 2,000/-
Institutional Support	Rs. 25,000/-	-	Rs. 25,000/-
Total	Rs. 8,05,200/-	Rs. 7,24,680/-	Rs. 80,520/-