

## CLINICAL RESEARCH STUDY ON JAPANESE ENCEPHALITIS

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### Introduction

Japanese encephalitis disease was described clinically in 1871. The virus was isolated from brain tissue in 1935 and mosquito transmission was proven in 1938. This virus causes disease in man, horses and pigs. The virus is widely distributed in Asia, from Japan and eastern Siberia to Indonesia & Westward to India. The annual morbidity exceeds 50,000 cases with highest incidence in temperate and sub-tropical regions of China, northern Thailand and India where epidemics occur in the summer months coincident with abundance of the principal vector *Culex tritaeniorhynchus*. The vector breeds in irrigated rice fields and the distribution of human cases is linked to exposure in this ecological setting. *Culex* vectors bite predominantly at sunset and sunrise. Children suffer the highest attack rates in endemic areas due to low immunity. Elderly non-immune people are at higher risk of severe disease than young adults.<sup>1</sup>

It emerged as a major health problem in India since 1970 when a series of epidemics occurred in various parts of the country. The earliest evidence of Japanese Encephalitis virus activity was obtained through serological surveys in 1952 and the disease was first recognised in 1955, when cases of Encephalitis were reported from North Arcot districts and neighbouring districts of Tamilnadu and Andhra Pradesh. Prior to 1970 disease was recorded only from South India. Later the epidemics were reported from West Bengal (1970, 1973) Madhya Pradesh (1980), Bihar (1980),

Assam (1977, 1980, 1986), Uttar Pradesh eastern U.P. (1980, 1991) and Goa (198). Fatality rate ranged between 21 to 44 percent.<sup>2</sup>

Central Council for Research in Homoeopathy conducted an epidemiological investigation of Japanese Encephalitis disease during the period 29th October, 1991 to 16th November, 1991 in the wake of reoccurrence of this epidemic in the four districts of Uttar Pradesh, Gorakhpur, Deoria, Maharajganj and Basti by a team of research workers. A genus epidemicus "*Belladonna*" was worked out after studying the signs and symptoms of the patients suffering from the disease. The total symptoms so obtained from all the patients were reperterised. The medicine "*Belladonna*" covered the uncommon, singular and characteristic disease symptoms i.e. totality of symptoms of the disease in different constitutions. A single dose of *Belladonna* 200 was distributed as preventive to 3,22,812 persons in 96 villages in three districts irrespective of their age which comprised the high risk group. This group formed the 12% of the total population of these districts. Follow up of 39,250 persons (12.15%) revealed no development of any signs and symptoms of Encephalitis. A total 237 patients (including 14 cases of the sequelae of Japanese Encephalitis discharged from various hospitals, primary health centres) were given symptomatic treatment with indicated homoeopathic medicines. Here also it was observed that 68.6% of the patients were relieved by *Belladonna*. The usefulness of "*Belladonna*" in both preventive and treatment aspect of Japanese

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Encephalitis has been observed during the study of this epidemic.<sup>2</sup>

The districts of Gorakhpur in Eastern U.P. have become endemic areas for this disease. Therefore, keeping in view the study conducted by CCRH in 1991 in these areas, a preliminary controlled study to see the effect of *Belladonna* as prophylactic in Japanese Encephalitis has been initiated. For this purpose a unit has been opened by CCRH in Gorakhpur. A protocol has been formulated and parameters defined for conduction of study and evaluation of results. A reporting and case recording proformae have also been formulated. This is a short-term study of 3-4 months duration but the results will be analysed after study for three consecutive years during the peak season.

#### PROTOCOL ON JAPANESE ENCEPHALITIS

Title of the project	Preliminary study of <i>Belladonna</i> as prophylactic in Japanese Encephalitis.
Name of the Instt./Unit	Clinical Research Unit (H) for Encephalitis, Gorakhpur (Uttar Pradesh).
Period	Three consecutive years during the peak season.
Date of inception :	
Proposed date of conclusion :	

#### Methodology

Initially two villages will be included in the study and the criteria for selection of particular village will depend upon the density of the cases of Japanese Encephalitis in previous epidemics. Since children are more prone to infection, all the children in the schools un-

der these two villages are to be given prophylactic. Simultaneously two neighbouring villages (control) are also to be surveyed. Prophylactic is to be given to all the children who will be covered under the inclusion and exclusion criteria.

#### Inclusion criteria

- i) Persons who did not suffer from Encephalitis during previous epidemics.
- ii) Persons who have not been inoculated with Japanese Encephalitis Vaccine.

#### Exclusion criteria

- i) Persons who earlier had an attack of Encephalitis in previous epidemics.
- ii) Persons suffering from any other systemic disease.
- iii) Persons who have developed the initial symptom of Japanese encephalitis.

Persons who are included into the study will be marked as exposed and unexposed on the following criteria :

*Exposed* - Persons who were exposed to the infection i.e. their family members suffered with Encephalitis during previous or recent epidemics.

*Unexposed* - Persons who were not exposed to the infection during previous or recent epidemics.

The prophylactic is to be given a month prior to peak season\*. *Belladonna* 200 single dose weekly for a month. A weekly follow up is to be recorded on the case recording proformae and report is to be sent after every epidemic by comparing the villages where no prophylactic has been distributed, in the reporting proforma.

(\* The peak season are September and October)

### Staff involved in the project

Since the study is short term and to be completed within a period of three months and large section of population is to be covered, it is therefore necessary for all the staff appointed in the unit to help in distribution of prophylactic, collection of data and frequent follow up.

### Assessment criteria

Weekly follow up on predesigned proforma for the cases under prophylactic and control group is to be carried out at least till three months after administration of the prophylactic and no. of cases infected with Japanese Encephalitis is to be recorded on the reporting proforma.

### Counselling for general measures to control the epidemic

1. Eliminating and reducing source of infection.
2. Interrupting transmission
3. Protecting persons at risk.

A small pamphlet in Hindi is to be printed for distribution amongst the population. It will also include the guidelines for taking homoeopathic medicine.

### REPORTING PROFORMA

1. Title of the project :
2. Name of the Instt./Unit :
3. Year of inception :
4. Period of reporting epidemic :
5. Total population of the village according to census :
6. No. of primary Health Centres in the villages :
7. Epidemics in villages during last one year:
8. Any family welfare/Health posters distributed :
9. Any orientation training camp held :

### 10. Comparison of report during the reporting epidemic

	Control	Prophylactic
Total no. of villages covered	—	—
Total no. of persons covered	—	—
Total no. of persons infected with Japanese Encephalitis	—	—
Total no. of persons not infected	—	—

- ### 11. Detailed report of infected persons
- |   | Control | Prophylactic |
|---|---------|--------------|
| i) Total no. of cases who had infection of Japanese Encephalitis after preventive | —       | —            |
| a) No. of cases exposed   | —       | —            |
| b) No. of cases not exposed   | —       | —            |

### Exposed Group

	Control	Prophylactic
Total no. of persons infected after one week of homoeopathic prophylactic	—	—

	Control	Prophylactic
After two weeks of homoeopathic prophylactic	—	—

	Control	Prophylactic
After three weeks of homoeopathic prophylactic	—	—

	Control	Prophylactic
After one month of homoeopathic prophylactic.	—	—

### Unexposed Group

	Control	Prophylactic
Total no. of persons infected after	—	—



	Control	Prophylactic
one week of homoeopathic prophylactic	—	—
After two weeks of homoeopathic prophylactic	—	—
After three weeks of homoeopathic prophylactic	—	—
After one month of homoeopathic prophylactic.	—	—
<i>Age incidence of infected cases</i>		
3 yrs to less than 6 yrs	—	—
6 yrs to less than 9 yrs	—	—
9 yrs to less than 12 yrs	—	—
12 yrs to less than 15 yrs	—	—

12. Follow up report of Infected persons

- i) No. of cases who developed prodromal symptoms of Japanese Encephalitis but recovered back to normal.
- ii) No. of cases who developed symptoms of Japanese Encephalitis but recovered without medicine.
- iii) No. of cases who developed Japanese Encephalitis and were referred to Hospital.

**DATA RECORD PROFORMA OF JAPANESE ENCEPHALITIS FOR PROPHYLACTIC STUDY**

Name	Age	Sex	Reg. No.
Address :	Occupation		Dated
Name of village			
Economic status : Very poor/poor/ middle/upper middle/rich			
Nutritional status :			

Epidemiological past history related to Japanese Encephalitis (Mark ( ) for relevant information).

1. Exposed

- |  |     |    |
|--|-----|----|
| a) Previous epidemic contact with Japanese Encephalitis patient (home or work place) | Yes | No |
| b) Exposed in (any body suffering or suffered in family) recent epidemic.            | Yes | No |

2. Not exposed

- a) Total no. of cases
- b) Total no. of cases who developed symptoms in recent epidemic.
  - i. Prodromal symptoms only
  - ii. Japanese Encephalitis

3. Homoeopathic prophylactic given on: Date

**FOLLOW UP SHEET**

- |   |                     |
|---|---------------------|
| 1. Area   | Case No.            |
|   | Date :              |
| 2. Date of Intake of Medicine                         |                     |
| a. Healthy  |                     |
| b. Symptoms of Japanese Encephalitis if developed any |                     |
| i. Day  |                     |
| ii. Symptom   |                     |
| c. Whether taken any other treatment                  |                     |
| 3. Counselling  | - Vector control    |
|   | - Disease control   |
|   | - Hygienic measures |
| 4. General comments on the case :                     |                     |

**References**

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3. WHO report on Japanese Encephalitis.