

# BIOScavenger Therapy in Organophosphate Poisoning

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| <b>Submission date</b><br>19/01/2009   | <b>Recruitment status</b><br>No longer recruiting                     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>28/01/2009 | <b>Overall study status</b><br>Completed                              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>28/01/2009       | <b>Condition category</b><br>Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Kishore Pichamuthu

**Contact details**  
Medical ICU  
Christian Medical College  
Ida Scudder Road  
Vellore  
India  
632004

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Open-label three-arm randomised controlled trial of fresh frozen plasma and albumin in the treatment of organophosphate poisoning: the BioSTOP (BIOScavenger Therapy in Organophosphate Poisoning) study

**Acronym**

BIOSTOP

**Study objectives**

To evaluate the effect of administration of fresh frozen plasma and albumin separately, as bioscavenger therapy, on biochemical and clinical outcomes in patients presenting with acute organophosphate (OP) poisoning.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Christian Medical College Vellore India ethics committee gave approval on the 23rd January 2007 (ref: RC Min No 6128)

**Study design**

Unblinded randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Organophosphate poisoning

**Interventions**

Treatment arms:

1. Fresh frozen plasma (FFP) (250 ml/bag): 4 bags on day 1 then 2 bags on day 2 and 3
2. 20% human albumin: 200 ml intravenous on day 1 then 100 ml on day 2 and 3
3. Control: do not receive either FFP or albumin. Common treatment: atropine and sedation schedule. No oximes are given.

Follow-up consists of clinical assessment and laboratory measurement of outcome measures.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Fresh frozen plasma, albumin

**Primary outcome(s)**

1. Lower the incidence of intermediate syndrome, measured during hospital stay and determined at discharge
2. Reduce effective circulating organophosphate levels, assayed directly and functionally and measured directly after the infusion of trial or placebo interventions

**Key secondary outcome(s)**

All measured during hospital stay and determined at discharge:

1. Reduce the need for invasive mechanical ventilation
2. Reduce mortality
3. Decrease Intensive Care Unit (ICU)/hospital length of stay
4. Reduce the duration of ventilation
5. The total dose of atropine required (daily and cumulative)
6. Temporal profile of organophosphate levels (total and functional), serum butyrylcholinesterase (BuChE) level
7. Adverse events and transfusion reactions

**Completion date**

03/03/2009

**Eligibility****Key inclusion criteria**

Patients (both males and females) above 15 years who present to the Emergency Department of Christian Medical College and Hospital (CMCH) with a diagnosis of organophosphate poisoning made on the basis of:

1. The typical clinical toxidrome of cholinergic and nicotinic manifestations
2. Reliable identification of the compound ingested based on the container brought by patient attendants or a subsequent confirmation by serum pseudocholinesterase levels of less than 1000 IU/L

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Those who present more than 12 hours after having consumed the OP poison ("late presenters")
2. Those who are suspected to have taken a combination of poisons/tablets along with the OP ("poly-substance overdose")
3. Those who are already treated with oximes in other hospitals prior to coming here ("prior oxime therapy"). This is because we do not want to have more than one intervention which can affect outcomes.
4. Those who are pregnant or lactating
5. Those who do not give consent for the study
6. Those who have a pre-existing volume overloaded state
7. Those who have a cardiac arrest within 15 minutes of arrival in the emergency department

**Date of first enrolment**

01/05/2007

**Date of final enrolment**

03/03/2009

## Locations

**Countries of recruitment**

India

**Study participating centre**

Medical ICU

Vellore

India

632004

## Sponsor information

**Organisation**

South Asian Clinical Toxicology Research Collaboration (SACTRC) (Sri Lanka)

**ROR**

<https://ror.org/04z435g27>

## Funder(s)

**Funder type**

Charity

**Funder Name**

International Collaborative Research Grant:

**Funder Name**

The Wellcome Trust (UK) (grant ref: 071669)

**Funder Name**

National Health and Medical Research Council (NHMRC) (Australia)

**Alternative Name(s)**

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Australia

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |