

BIOscavenger Therapy in Organophosphate Poisoning

Submission date 19/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/01/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/01/2009	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2007

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

Age group

Adult

Sex

Both

Target number of participants

60

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)

Sponsor details

Faculty of Medicine

Peradeniya University

Peradeniya

Sri Lanka

20400
+94 (0)81 447 9822
enquiry@sactrc.org

Sponsor type

Research organisation

Website

<http://www.sactrc.org>

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)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration