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BIOScavenger Therapy in Organophosphate Poisoning

Submission date	Recruitment status	[ ] Prospectively registered
19/01/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/01/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/01/2009	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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