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Acute organophosphate pesticide poisoning in Sri Lanka: management, complications and pharmacogenetics

Submission date	Recruitment status
29/07/2002	No longer recruiting
Registration date	**Overall study status**
29/07/2002	Completed
Last Edited	**Condition category**
17/02/2015	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

GR063560

Study information

Scientific Title
Acute organophosphate pesticide poisoning in Sri Lanka: management, complications and pharmacogenetics

Study objectives
We propose to carry out a randomised controlled trial of single or multi-dose activated charcoal regimens in Sri Lankan patients presenting with a history of acute poisoning. The study will look at unselected adult patients with most forms of acute poisoning.

The main hypothesis is that the multi-dose activated charcoal regimen will reduce the case fatality rate from 10% to 7%, hence the first principal comparison will be multi-dose activated charcoal versus no intervention. The potential of multidose regimens to work long after ingestion - due to interruption of enterohepatic circulation and gut dialysis - means that such a regimen is more likely to work in a situation where people typically present several hours after ingestion.

We suspect that a single dose will be less effective since most absorption will have taken place by the patient's presentation to hospital. Therefore, the second principal comparison will test the hypothesis that the case fatality rate in patients receiving a single dose of activated charcoal is equal to that in patients receiving multiple doses.

In order to investigate whether a single dose of activated charcoal has a similar effect as giving no intervention, the third principal comparison will test the hypothesis that the case fatality rate in patients receiving a single dose of activated charcoal is equal to that in patients receiving no intervention.

It is possible that both treatment regimens, if effective in reducing case fatality rates, will be more effective the earlier they are started. Therefore we will assess the trends in clinical effectiveness according to time post-ingestion to start of therapy.

In order to determine whether treatment should be started irrespective of severity, we will also assess trends in case fatality rates across a gradient of severity.

Admission blood samples will be retrospectively analysed to determine the identity of the poison ingested. The primary analyses will then be repeated with correction for the identity of the poison.

Subgroup analyses are planned to look at the consistency of treatment effect across different types of poison i.e. dimethylated and diethylated Organophosphate (OP) pesticides, organochlorines, all pesticides, and yellow oleander. These will be carried out for the primary outcome and secondary outcomes, plus trends with time and severity.

Please note that this RCT has a nested study registered under ISRCTN55264358. For more details on this nested study please visit http://www.isrctn.com/ISRCTN55264358.

The overall trial end date has been extended from 31/10/2004 to 01/12/2004.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute self-poisoning in the developing world

Interventions
No charcoal, single 50 g dose of superactivated charcoal, multiple doses (6 x every four hour doses of superactivated charcoal).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Activated charcoal

Primary outcome measure
All-cause mortality at hospital discharge.

Secondary outcome measures
Organophosphate pesticides:
1. Percentage of patients requiring intubation
2. Period of ventilation
3. Percentage of patients developing the intermediate syndrome (cranial nerve palsies and/or proximal weakness, without distal weakness, after resolution of the cholinergic crisis)

Organochlorine pesticides:
Incidence of status epilepticus (continuous overt generalised seizure activity for mroe than five minutes or two generalised seizures without an intervening recovery of consciousness)

Yellow oleander:
1. Cardiac dysrhythmias requiring anti-digoxin Fab (3° heart block, Mobitz type II 2° block, sinus bradycardia with heart rate less than 35 bpm, and sinus arrest or block with sinus pauses more than 3 seconds), or
2. Serum potassium greater than 6.0

Overall study start date
31/03/2002

Completion date
01/12/2004

Eligibility

Key inclusion criteria
All patients presenting with a history of acute self-poisoning in selected Sri Lankan hospitals

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
4650

Key exclusion criteria
We hope to recruit all patients admitted to the medical wards with a history of acute poisoning, except for those:
1. Under the age of 14 years
2. Known to be pregnant
3. Who have ingested hydrocarbons alone or corrosives (good prognosis for former, charcoal contraindicated for latter)
4. Who require oral medication
5. Who present more than 72 hours post-ingestion
6. Patients under the age of 16 or unconscious, who are present without relatives

Date of first enrolment
31/03/2002

Date of final enrolment
16/10/2004

Locations

Countries of recruitment
Scotland

Sri Lanka

United Kingdom

Study participating centre
Scottish Poisons Information Bureau
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	study protocol:	11/05/2007		Yes	No
Results article	results:	16/02/2008		Yes	No