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A randomised controlled trial of high-dose immunosuppression in paraquat poisoning

Submission date	Recruitment status	[X] Prospectively registered
31/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/07/2021	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
071669

Study information

Scientific Title
A randomised controlled trial of high-dose immunosuppression in paraquat poisoning

Study objectives
To assess whether intravenous cyclophosphamide and methylprednisolone, followed by dexamethasone, as supplementary therapy to a single dose of fullers earth or activated charcoal, prevents death from paraquat-induced lung fibrosis.

Please note that as of 15/01/2009 this record was updated to include an extended anticipated end date of 30/12/2010. The initial anticipated end date of this trial was 30/12/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Faculty of Medicine, University of Ruhana gave approval on the 18th April 2006

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Paraquat poisoning

Interventions
Two days of cyclophosphamide 750 mg (if weight is less than 50 kg) or one gram (if weight is more than 50 kg), and three days of methylprednisolone one gram both by intravenous infusion over one hour. Steroids in the form of oral dexamethasone (8 mg three times daily) will be continued for the next two weeks. Patients will receive mesna 400 mg intravenous at start of therapy and four and eight hours later to reduce risk of haemorrhagic cystitis.

Control patients will receive saline placebo infusion and placebo capsules.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cyclophosphamide, methylprednisone, dexamethasone, fuller's earth or activated charcoal

Primary outcome(s)
All-cause mortality in hospital

Key secondary outcome(s))
1. All-cause mortality at three months post-ingestion
2. Lung function in survivors at three months

Completion date
30/12/2010

Eligibility

Key inclusion criteria
1. Patients with a history of acute paraquat poisoning
2. Presenting within 24 hours of paraquat ingestion with evidence of paraquat intoxication by urinary dithionite test

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
299

Key exclusion criteria
1. Under 14 years
2. Pregnant
3. Systolic blood pressure of less than 70 mmHg, unresponsive to one litre fluid challenge, Glasgow Coma Score (GCS) less than 8/15, or cyanosis
4. Already received cyclophosphamide or methylprednisolone for this episode of poisoning
5. Allergic to cyclophosphamide, methylprednisolone, dexamethasone or mesna
6. Unable to give consent, or not accompanied by a relative, where the hospital consultant prefers that consent be obtained from a relative rather than the consultant looking after the patient
7. Present more than 24 hours after paraquat ingestion

Date of first enrolment
30/08/2006

Date of final enrolment
30/12/2010

Locations

Countries of recruitment
Sri Lanka

Study participating centre
SACTRC
Peradeniya
Sri Lanka
20000

Sponsor information

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

ROR
https://ror.org/04z435g27

Funder(s)

Funder type
Industry

Funder Name
Syngenta Crop Protection AG (USA)

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

Results and Publications

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?
Results article		01/07/2018	01/07/2021	Yes	No