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Gastric Lavage in unselected acute organophosphate poisoning (OP)

Submission date	Recruitment status	[X] Prospectively registered
28/11/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/09/2021	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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Study information

Scientific Title
Gastric Lavage in unselected acute organophosphate poisoning (OP)

Acronym
GLAOP

Study objectives

Gastric lavage, one of the most convenient methods, is a routine first aid procedure in P.R. China and many Asian countries. But it is the opposite case in the developed countries. We are told that gastric lavage should not be used unless two criteria are met: it should be used within an hour of ingestion of the poison, and the amount of toxin should be substantial. It is believed that if the patients come too late, the stomach contents may have passed into the small bowel and gastric lavage would not be expected to retrieve such material. In addition, gastric lavage may push the gastric contents beyond the pylorus, which enhances the absorption. It is prudent to do it internationally also because there are many complications during the procedure. The complications include inspiration, pneumonia, arrhythmia and so on.

At the same time, we should take note that the evidence on which the European and American guidelines have been created is largely from the developed countries and involves overdoses of pharmaceutical agents. Recent systematic reviews by international toxicological societies were unable to find any evidence from the clinical poisoning trials that gastric lavage is completely useful. All the reports are drawn from the trials from drug overdose or volunteers taking tablets. Reports from the animal tests have shown that gastric lavage is definitely beneficial for liquid poisons. Liquid poisons are more easily aspired than tablets. Till now there has been no randomised controlled trial about gastric lavage. Little clinical evidence favours or opposes it, so our trial is needed.

Deliberate self-poisoning has reached epidemic proportions in parts of the developing world where highly toxic poisons and sparse medical facilities ensure a high fatality rate. Pesticides are the major problem - the World Health Organization (WHO) estimates that they cause more than 220,000 deaths worldwide each year, most due to organophosphate insecticides. Organophosphate Poisoning (OP) is a serious event with very high mortality, about 15% to 20%, so OP patients but not the drug overdose ones are enrolled. The concentration of organophosphate in the stomach is found to still be very high after several hours or even several days during the clinical work in China. Thus it seems that there are more reasons for gastric lavage in OP patients.

Gastric lavage is a two-sided sword in the treatment of organophosphate poisoning. Because we cannot do the trial with no lavage at all, we will compare the two groups to shed some light on the role of lavage. The results of the trial may give some evidence for the role of lavage i.e. which outweighs more. If triple gastric lavage can be proven to be the effective outweighing complication, then lavage may be an extremely valuable therapy since it is widely available in the developing world, relatively cheap, useful for many poisons and safe once the airway is protected. On the other hand, if it is shown to be ineffective or the complications outweigh the effect, then millions of Yuan currently being spent on gastric lavage may be diverted to other more effective interventions. At the same time, it does not need to be done with the probability of serious complications. Thus gastric lavage will not be done as a routine procedure.

The main hypothesis is that triple gastric lavage will reduce the case fatality rate; hence the first principal comparison will be triple gastric lavage versus single gastric lavage. The potential of triple regimens to work long after ingestion - due to the high concentration of gastric content - means that such a regimen is more likely to work in a situation where people drink lots of OP.

It is possible that a triple gastric lavage will be more effective in reducing case fatality rates, the earlier they are started. Therefore we will assess the trends in clinical effectiveness according to time post-ingestion to the 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 analysis will then be repeated with correction for the identity of the poison.

Ethics approval required
Old ethics approval format

Ethics approval(s)
An independent Data Monitoring and Ethics Committee (DMEC) has been established for the trial. Date of approval: 20/11/2005.

Study design
An interventional study. Open randomised controlled trial with two parallel groups: single gastric lavage versus triple gastric lavage.

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients will receive gastric lavage on admission irrespective of whether they have had experience of it or not. Because of the ethical problem in China, we will not analyse the OP patients with no gastric lavage treatment at all.

Gastric lavage will be performed as follows. At admission, patients will be placed in the left side prone position; the tube is then put through the nose. The tube is confirmed in the stomach by pulling out gastric content or if a sound is heard in the stomach area. The gastric content is sucked out first and then 300 ml warm water is pushed in. Then sucked out completely and pushed in. The above procedures are repeated until the aspired water is clean and without smell. The end point is judged by at least two doctors. The above procedure will be repeated 4 and 8 hours respectively after admission into the triple lavage group. 24 hours after the admission (gastric lavage in all groups will have been finished), the gastric tube will not be pulled out unless it is necessary.

Serious complications such as bradycardic vasovagal response, oesophageal rupture and aspiration will be monitored throughout the procedure; the procedure will be done by skilled medical staff. The lavage will be stopped as soon as any serious complication happens.

A 10 ml blood sample with Ethylenediamine Tetraacetic Acid (EDTA) anticoagulation will be taken using sterile syringes and needles from each patient at admission. Further 10 ml blood samples will be taken at 12 and 24 hours post-admission. Whether a needle or indwelling cannula is used will be determined by the wishes of the patient. The contents of the stomach will be drawn at the same time as the blood samples are taken. Samples of both the plasma and the stomach will be stored at -20 °C, and will be checked altogether for the concentration by Solid Extraction - Gas Chromatography. The specific identity and blood concentration of the poison will be assayed retrospectively. Sample analysts are blinded to allocation of the group.

All the vital data and the blood acetylcholinesterase enzyme activity will be analysed. Time for the 50% recovery of the blood acetylcholinesterase enzyme activity will be recorded. Throughout the trial, the patient will remain under the responsibility of the admitting medical consultant. The standard treatment will be done according to the protocol. Both study and host hospital clinicians will report to this doctor.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
All-cause mortality at hospital discharge.

Key secondary outcome(s))
1. % of patients requiring intubation because of the respiratory failure
2. Period of ventilation
3. % of patients developing the intermediate syndrome (cranial nerve palsies and/or proximal weakness, without distal weakness, after resolution of the cholinergic crisis)
4. Number of the organ dysfunction and 50% recovery time for blood acetylcholinesterase enzyme activity

Completion date
01/03/2009

Eligibility

Key inclusion criteria
All patients admitted to the medical wards with a history of acute organophosphate poisoning through stomach

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Under the age of 18 years
2. Known to be pregnant
3. Have ingested other kinds of poison at the same time

Date of first enrolment

01/03/2006

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
China

Study participating centre
Emergency Department
Beijing
China
100730

Sponsor information

Organisation
Peking Union Medical College Hospital (China)

ROR
https://ror.org/04jztag35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Peking Union Medical College Hospital (China) - Emergency Department

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?
Protocol article		19/10/2006	01/09/2021	Yes	No