Registration study on the Application of intravenous lipid emulsion in patients with acute poisoning

2021-11-12

Informed consent

Research Project title: A registered study on the application of intravenous lipid emulsion in patients with acute poisoning

Principal investigator: Liyi

Department Telephone number: 15098750165

Research Institute: Emergency Department of Peking Union Medical College Hospital

1. Research Background and Purpose:

Fat-soluble drugs and organophosphorus pesticide poisoning poses a serious threat to life safety of patients, due to its rapid onset and progression of, if not timely take quick and effective treatment measures, usually led to the deaths of patients, the clinical adopt regular treatment, while the conventional treatment in some patients to achieve a certain effect,However, there are still hemodynamic instability, shock, malignant arrhythmia, continuous convulsions and other serious life-threatening conditions after treatment, and there is no effective and convenient treatment at present.Vein with fat emulsion (intravenous lipid emulsion, ILE) used in the treatment of cloth than the original because of local anesthetics, later also used to treat a variety of other lipotropy drug poisoning.The research on ILE treatment is still in the

preliminary stage and relatively limited, and there is not enough evidence of evidence-based medicine at present. Systematic evaluation of the treatment of acute poisoning by fat emulsion found that the overall quality of the research supporting this treatment was low or very low, but the included case reports showed that,Fat emulsions have some benefit in patients with verapamil, beta-blockers, certain tricyclic antidepressants, bupivacaine, chlorpromazine, and certain antiarrhythmic drugs (e.g., flucarni) poisoning.ILE may help treat hemodynamic instability in patients who have been poisoned by these drugs.

Research objectives :(1) to study the therapeutic effects of ILE on patients' circulatory system, cardiovascular system and central nervous system before and after the treatment of fat-soluble drugs and organophosphorus pesticide poisoning.(2) Through the collection of clinical data, we can obtain enough evidence-based medical evidence.(3) Further elucidate the related mechanisms of ILE in the treatment of fat-soluble drug poisoning.(4) Standardize the relevant process of ILE detoxification treatment to benefit more patients.(5) Further explore the adverse reactions and coping strategies of ILE treatment.

2. Research contents, methods and procedures:

Fat-soluble drugs and organophosphorus pesticide poisoning

are often life-threatening and usually lead to death. Intravenous fat milk is used as a life-saving measure only when patients are still in critical condition such as circulatory failure after conventional treatment.This registered experiment will collect the data of all patients with fat-soluble drugs and organophosphorus (fat-soluble) pesticide poisoning conforming to ILE detoxification treatment without interfering with clinical treatment. That is, after obtaining your informed consent,Determination of ILE blood drug concentration changes after treatment, stable cycle time, arrhythmia, recovery time and before and after treatment of the cardiovascular system, central nervous system and so on various system recovery and the information such as the final outcome, judge ILE detoxification treatment effectiveness, to clarify the precise mechanism of ILE treatment, seeking the best dosage form and dosage regimen, reduce adverse reactions.

3. **Possible risks (or discomfort or inconvenience) and benefits (benefits for individuals or social groups) of participating in the study:**

Potential risks: Participating in this study is an observational study and does not interfere with the clinical diagnosis and treatment of patients, so there will be no additional impact or risk on the outcome and prognosis of patients.The potential risks of this

study are routine diagnostic and treatment risks of ILE treatment, and participation in this study does not increase other related additional risks of patients.

benefit:Through the collection of fat milk detoxification cases in major hospitals, it is helpful to collect sufficient evidence-based medical evidence, clarify the exact mechanism of ILE2 treatment, seek the best dosage form and administration plan, reduce adverse reactions, and verify its efficacy through later controlled experiments, so as to facilitate the promotion of ILE treatment.To develop reasonable, convenient and effective programs for the rescue of patients suffering from fat-soluble drugs and organophosphorus pesticide poisoning. Although you will not benefit directly from participating in the experiment, your participation will have far-reaching significance for subsequent medical research and have considerable social benefits.

Consultation about the content: You have the right to consult about the research content, consultation telephone: 15098750165;You have the right to consult the Ethics Review Board at 010-69156874 about your rights or related risks.

4. **Right to withdraw from study:**

Your participation in this study is entirely voluntary.Your unwillingness to participate in or continue to participate in the

study for no reason whatsoever will have no effect on your interests.In addition, you may withdraw from the study at any time.Your doctor or researcher may also ask you to withdraw if you do not follow the doctor's instructions or if your doctor has your health and benefits in mind.

5. **Investigate the compensation of compensate research:**

fat-soluble drugs or organophosphate poisoning patients complicated and serious, there is a great danger, intravenous fat emulsion was used as save life in patients with terminal measures, for poisoning patients dying last hope, in the process of clinical treatment of treatment, this method is adopted as your treatment plan.This clinical trial is an observational study. The purpose of our study is to observe the relevant situation of fat milk treatment and obtain relevant data in the treatment process. It does not interfere with your normal treatment process and will not bring additional risks, so it does not involve related compensation issues.

6. Confidentiality:

The medical information you receive from the study will be kept confidential.Research results published in academic journals will not reveal any information that can personally identify you.The Peking Union Medical College Hospital will keep all records of your participation in this study as well as relevant hospital and office

records, and no one may access this information without authorization.

7. This informed consent is made in duplicate, with one copy for the subject and one copy for the investigator.

Informed consent of the subject:

I have read and fully understood the above contents, and have carefully considered the above contents, especially my rights, risks and benefits of participating in this study.I volunteered to participate in the study and cooperate with the researchers.I also declare that I can withdraw from this study at any time for any reason without losing any legal rights.

Subject's signature: Date:

Parent/Legal Guardien : Date:

Relationship with patient: Date:

Investigator's name : Date: