What will a patient have to do to enter the study?

If a patient is willing and can be in the study, an informed consent form must be signed. The person signing the consent may be the patient or the legally authorized representative. The informed consent describes the study and explains that the participant is being asked to volunteer for this research study.

Can the study participant withdraw from the study?

Participation in this study is completely voluntary. The patient or legally authorized representative has the right to refuse to be in the study. This refusal will not affect the patient's hospital care in any way. The study participant can choose to stop participating anytime after giving consent. This decision will not affect in any way the participant's current or future medical care or any other benefits to which the participant is otherwise entitled. The study researchers may stop the study participant from taking part in this study at any time if they decide it is in the participant's best interest.

What happens if the study participant is discharged from the SICU?

If the study participant is moved from the SICU to a regular room in the hospital, he/she will still be enrolled in the study. Regular blood draws will still be done on days 1, 3, 7, 14, 21, and 28 of the study.

What happens if the study participant is discharged from the hospital?

If the participant is discharged from the hospital before day 28 of the study, study drug will be stopped. Blood collection on the appropriate days will continue. In this case, the participant will be asked to come to a designated location for the scheduled blood draws.

What is the study team's responsibility if someone agrees to be a participant?

The study team will oversee the nutrition care for 28 days and communicate with the participant's physicians. All nutrition will be given using methods that are standard around the world. Medical records will be checked regularly and kept private to the extent allowed by law. A study number will be used rather than a name on study records wherever possible. The study team will do this even if outside review occurs.

Who will make sure that the study is conducted safely?

The National Institutes of Health, a medical safety monitor, and a board of experts will closely monitor the study.

Why participate in the GLND study?

The best reason to volunteer for the GLND study is to be a part of a clinical study designed to provide answers about whether GLND improves the health of SICU patients. The results may not directly benefit the person participating in the study but may help patients in the Surgical Intensive Care Unit in the future.

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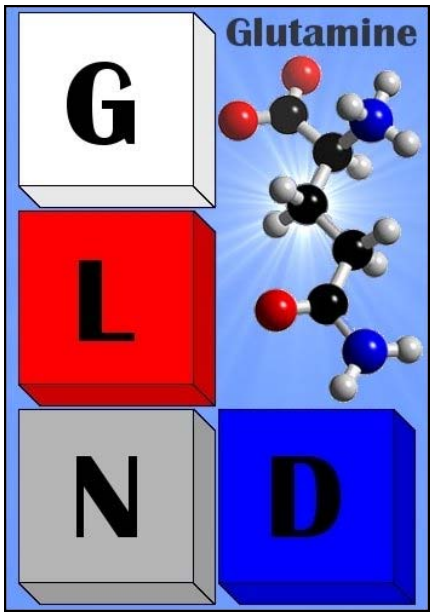

Efficacy and Mechanisms of GLN Dipeptide (GLND) in the SICU

A National Institutes of Health Funded Multi-Center Research Study

INFORMATION FOR PATIENTS & FAMILIES

1.

What is Glutamine Dipeptide (GLND)?

GLND is a small protein made of two naturally occurring amino acids named glutamine and alanine. Glutamine is normally made in the body and can be found in our diet. This protein is important to the immune system during illness and stress. During illnesses, the body may not make enough glutamine to satisfy the body's needs.

What is PN?

PN is **P**arenteral **N**utrition or intravenous nutrition. PN is a standard of care method for feeding patients who are unable to get all of their nutrients either by eating or by being fed through a tube in the stomach (tube feeding). Patients receive PN through a needle in a blood vessel (intravenous feeding). PN is commonly used to feed patients in the Surgical Intensive Care Unit (SICU).

What will this study investigate?

This study seeks to find out if adding GLND to PN improves health and lowers the number of infections in patients admitted to the SICU who need intravenous feeding. The study will also try to see if patients get better faster and spend less time in the hospital.

Who can be in this study?

A patient has to be at least 18 but not more than 80 years of age and be admitted to the SICU. The patient has to have had heart, blood vessel, or intestinal surgery and will need intravenous nutrition for at least seven days to be in the study.

2.

Who are the researchers?

The members of the study team are the study doctor, study coordinator, nutrition support team members, and pharmacists. Members of the study team are experts in nutrition support for hospitalized and surgical patients.

What will happen during the study? How long does the study last?

Each participant will be in the study for six months. The study team will manage the intravenous nutrition and tube feedings for a maximum of 28 days. Study blood tests will be done on days 1, 3, 7, 14, 21, and 28. If the participant goes home before 28 days, blood samples for the days listed will still need to be obtained. Brief follow-up phone calls to the household will be made after 2, 4, and 6 months.

How often will the study participant be monitored?

The study team will manage the nutrition care with the participant's doctor (s) for up to 28 days. If the participant needs nutritional care after 28 days, a nutrition support team outside of the study will continue to provide it. Study personnel will review medical records regularly. Participants will be followed as usual during their hospitalization.

3.

Which treatment will the study participant receive?

The participant will be selected by chance (like a flip of a coin) either to receive GLND in the PN or not to receive GLND. Both fluids (with or without GLND) will have the same amount of calories, protein, fat, vitamins, minerals, and electrolytes. The researchers and the participant or their legally authorized representative will not know whether GLND was part of the PN or not until the study is over. The study pharmacist(s) who prepares the fluid will know what is being given.

What are the risks of this study?

The amino acid glutamine has been shown to be safe for patients in many studies. GLND has been approved for use in hospitals and home patients in other countries but not in the United States. Potential unknown risks are possible. Laboratory tests may require drawing blood from a vein with a needle. In this case, there may be some pain, bruising, and soreness. The total amount of blood taken over a 28 day period is unlikely to cause significant low blood count (anemia).

What costs are involved?

The participant will not be charged for any study activities nor will he/she be paid for being in this study. Parking passes and meal coupons may be available if the participant needs to return for blood samples after hospital discharge.