Immunonutrition Supplementation for Improved Burn Wound in Healing in Older Adults

NCT04725071

12/20/2023

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants:
Will a specialized nutrition supplement improve burn wound healing in older adults?

Formal Study Title:
Immunonutrition Supplementation for Improved Burn Wound in Healing in Older Adults

Lead Researcher:
Rebecca Busch, MD
Phone: 608-265-9574
Email: busch@surgery.wisc.edu

Where Lead Researcher works:
Department of Surgery, University of Wisconsin Health

_____ _____
Participant name Medical Record Number

Invitation

We invite you to take part in a research study about using a specialized supplement to see if it improves burn wound healing. We are inviting you because you have experienced a burn injury and are at least 55 years old.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to assess if a specialized nutrition supplement has an impact on burn wounds in older adults. We are doing this research because this supplement has proven benefits in patients with chronic wounds and similar conditions. Older patients with burns are at increased risk of prolonged wound healing and a slower return to normal activity. We propose that this supplement may make wound healing faster which would result in a faster return to normal life and shorter hospital stay.

This study is being done at the University of Wisconsin Burn and Wound Center. A total of about 20 people will participate in this initial study.

Supplements for this study are being provided by Nestle Corporation.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to drink a supplement along with your normal food while you are inpatient at the UW Burn and Wound Center. The supplement that you are given will be randomly assigned for the duration of your hospital stay, as with the flip of a coin. You will receive a supplement either two or three times per day for the first week of your stay and once daily for every day after that. The supplements are only provided while you are inpatient. You do not have to drink the supplement if you are feeling unwell or not hungry. The amount you drink will be recorded in the medical chart with your daily calorie counts as is standard at the Burn and Wound Center. If you want additional supplements, you may ask for them, but will only receive standard supplements. You will know if you are receiving a specialized supplement or the standard supplement that all burn patients receive.

There are no other specialized interventions you will need to take part in if you agree to participate in the study. You will receive the standard of care for your burns if you choose to participate or not.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Things you tell the researchers about your health
- Medical and surgical history
- Nutritional information including how much you eat every day and your weight

- Surgical records that relate to your burn wound
- Burn photographs which are in the chart (no extra photographs will be obtained)
- Medical diagnoses during your treatment of your burn
- Information regarding infections (ex. Culture results and antibiotics) while you have a burn
- Basic lab tests

How long will I be in this study?

You will be part of the study for about 3 months, but possibly up to 1 year. You will only need to take the supplements while you are in the hospital for your burn, which is typically 1-2 weeks. The research team will access your outpatient Burn Clinic follow up notes to assess your progress with burn healing and continue to follow your records until you have resolution of your burn wound, up to 1 year.

The researchers may take you out of the study, even if you want to continue, if:

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

How is being in this study different from my regular health care?

People with burn wounds usually get standard Boost nutritional supplements in addition to their normal meal trays to help with calorie and protein intake. In this study, some people will get this standard treatment, and others will get the specialized supplement which contains additional additives which may help with wound healing instead. There is roughly the same amount of protein and calories in the standard and specialized supplement. Participants will know if they are receiving the standard supplement or the specialized supplement.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until study research is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researcher team by writing to the Lead Researcher, Rebecca Busch at busch@surgery.wisc.edu

Will being in this study help me in any way?

Being in this study may help you heal your burn wound more quickly and therefore return to your normal activity faster. If you are in the group that gets study treatment, this may work better than the standard treatment for your condition, but we cannot promise this will happen. The study treatment might not work at all, or it might have bad side effects though rare. If you are in the group that gets standard care, we do not expect you to get any additional health benefit from being in the study. Your treatment will be the same as you would get outside of this study. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about the impact of this specialized supplement in the care of older burn patients.

What are the risks?

The supplement being investigated in this study has been shown to be safe for the general population and in patients with chronic wounds. The specialized nutrition supplement has similar protein and calorie content to our regular supplements that all burn patients receive. It is possible that you will not like the taste of whichever supplement you receive. An extremely rare risk would be an allergic reaction to the supplement. This is highly unlikely and would be treated promptly as you would be in the hospital at the time it occurs should that happen.

There is a risk that your information could become known to someone not involved in this study.

Will being in this study cost me anything?

There will be no cost to you for the supplements you receive that are for research purposes only and are not part of your regular care.

You or your insurance company will have to pay for all costs for medical care related to your burn injury, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your primary care provider or call the UW Burn and Wound Clinic for burn related issues
- Call the Lead Researcher, Rebecca Busch at 608-265-9574 to report your sickness or injury.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for

monitoring this study. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you or your legally accepted representative are authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Will information from this study go in my medical record?

- A medical record will be created for you if you do not already have one. The specific supplement you receive to will not go in your medical record. The information collected for this study will already be in your medical record as part of standard of care and documentation for all burn patients. Both you and your UW Health providers will be able to see these results.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen to my data after my participation ends?

We will keep your data for a planned 5 years following the completion of this trial. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers.
This is what will happen with your banked data:

- We will use the data in future research projects about the use of nutrition supplements for burn wound healing. We may also use them for other types of research.
- The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.

- The banked data will be labeled with a code instead of your name.
- When we give your data to other investigators for research projects, they will not be able to use the code to figure out which data are yours.
- The research team will maintain a link between your data and your identifiable information kept by the study team.
- You can request to have your data removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data:

- Banked data will not be shared with your health care providers or used in your treatment outside this study.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Rebecca Busch at 608-265-9574 or busch@surgery.wisc.edu. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov (NCT04725071), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Signature Page – Patient Providing Consent

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of Research Participant

_____

Signature of Research Participant Date

_____

Signature of Person Obtaining Consent and Authorization Date

Signature Page – Patient Providing Consent

In the event that you are unable to make decisions for yourself sometime during this hospitalization, please indicate how you would like us to manage your study participation:

☐ Continue my participation in the study.

☐ Defer continued participation in the study to my Legally Authorized Representative.

Printed Name of Research Participant

Signature of Research Participant Date

Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****

Signature Page – Legally Authorized Representative Consent

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Printed Name of Research Participant

Signature of Legally Authorized Representative Date
(Print name if consent provided on phone)

Signature of Person Obtaining Consent and Authorization Date

Signature of Witness Date

****You will receive a copy of this form****