Methylglyoxal Evaluation in Humans (MEH)

A Cross-Sectional Trial of Methylglyoxylated-Protein Levels in Adults with Chronic Pain

(NCT Not Yet Assigned)

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RESEARCH CONSENT FORM

Methylglyoxal Evaluation in Humans

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- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

Dr. Wright is doing the study at the University of Kansas Medical Center (KUMC). About 45 people will be in the study.

Why is this study being done?

We are performing this study to compare chronic nerve pain in people who have type 2 diabetes and in people with low back pain. Our study is specifically interested in methylglyoxal (MGO), a molecule naturally produced in our body. Emerging research suggests that high MGO levels in blood is associated with increased pain. By doing this study, researchers will better understand what types of pain are associated with increased MGO. The study will test whether patients with low back pain caused by lumbar disc herniation will have elevated MGO levels in the blood, and if so, are they comparable to patients with type 2 diabetes and painful neuropathy. Finally, this study will also tell us if MGO can serve as a blood biomarker for pain, which will be helpful in future studies with new pain treatments.

How long will I be in this study?
The study will involve 1 visit to the KUMC Clinical and Translational Science Unit (CTSU) on the main medical center campus.

What will I be asked to do?
All study participants, regardless of healthy, diabetic, or low back pain status, will complete identical study tasks. If you decide to be in the study and are eligible, the researchers will ask you to complete one clinic visit (1 hour) which will include the following:

- You will first review the Informed Consent Form and discuss it with research staff. If you decide that you want to participate, you will be asked to sign the form.
- You will be asked about any medications you are currently taking.
- You will be asked to complete 4 surveys which ask questions about your demographics, general pain levels, quality of life, and whether you experience neuropathy. These surveys will help us understand how your health may affect your blood draw results.
- You will have your height and weight collected.
- You will have blood collected for the following tests: HbA1c and hemoglobin, Methylglyoxal proteins (MGO), Neurofilament Light Levels (NFL), and Glyoxalase (GLO1). The purpose of blood collection in our study is to help us understand the relationship between MGO levels and chronic pain levels.

What are the risks of being in the study?
Risks of blood draws include temporary discomfort from the needle being inserted into the skin. There is also low risk of bruising, swelling, or in rare cases, infection or blood clot at the blood draw site.

Some questions on the questionnaires may cause feelings of embarrassment and make you uncomfortable.

There is a small risk of breach of confidentiality. For that reason, your information will be protected as described in the Privacy section below.

Are there benefits to being in this study?
You will not get personal benefit from being in this study. Researchers hope this study may be helpful in improving treatments for patients with chronic pain.

Will I have any costs or payments for being in the study?
You will receive $50 for the visit.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number,

and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

What other choices do I have if I don't want to be in the study?
You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC.

How will my confidentiality and privacy be protected?
The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Wright and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

All study information that is sent outside KU Medical Center will have information that could easily identify you (such as name and address) removed. By limiting the information that is released, we are lowering the risk that your identity could be discovered and used for unauthorized purposes.

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Dr. Wright. The mailing address is Dr. Wright, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas

City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you. They are permitted to use and share information that was gathered before they received your cancellation.

What if I decide to leave the study?
You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Wright using the contact information on the first page of this document. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you. They are permitted to use and share information that was gathered before they received your cancellation.

Will I be told about research results?
Research results will be available to you once the study is completed.

How will my research information and specimens be used in the future?
Information and specimens used in this study will not be used for future purposes.

Who can I talk to about the study?
Dr. Wright or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or IRBhelp@kumc.edu.

CONSENT
Dr. Wright or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____	_____	_____
Signature of Participant	Time	Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

In the future, the researchers may conduct additional studies about chronic nerve pain. If you agree, the researchers will contact you to see if you want to join future studies. You would receive a separate consent form describing the future studies.

☐ Yes, I would like to be contacted if I qualify for future studies. _____
Signature

☐ No. Please do not contact me about future studies. _____
Signature