AIHA Patient Registry

Primary Investigator: Craig Lammert

Study investigators: Erin Anderson
John Guardiola
Kelsey Green
Regina Weber

Introduction and Background

Autoimmune hepatitis (AIH) is liver inflammation that occurs when the body's immune system turns against liver cells. It is caused by an overactive immune system that attacks normal liver cells because it mistakes them for foreign agents such as viruses or bacteria. AIH can present in all ages and ethnic populations, but women seem to be more affected by the disease than men. AIH is not contagious but is a chronic disease that is treated long-term, often for life. There is no cure for AIH, but the disease can be controlled through medication. Untreated autoimmune hepatitis can lead to scarring of the liver (cirrhosis) and eventually to liver failure. The exact cause of AIH is unclear, but genetic and environmental factors, especially in people who seem to be genetically susceptible to autoimmune disorders, may play a role in triggering the disease.

The Autoimmune Hepatitis Association (AIHA) is a not-for-profit organization with a mission to provide support and hope to patients and families affected by AIH through disease education and research opportunities. It has a membership of more than 2,000 patients and family members, most of whom live in the United States and Canada. Through webinars, conferences, support groups, its website and blog, the AIHA provides a wealth of information about AIH and related health topics. The AIHA has helped foster a community for affected individuals and their families to learn about the disease and to share their knowledge. The AIHA has a large social media presence, which it has used in addition to its membership database to successfully recruit patients for research studies.

One of the goals of the AIHA is to develop a patient registry for people who are affected by AIH. This patient-focused registry seeks to obtain data, including patient demographics, medications, and biopsy results, to begin to characterize this little understood disease. Additionally, data from health quality of life questionnaires relating to symptoms, diet, pain, activities, and mental health will be collected.

Recruitment of participants may take place via email, mail, in-person and virtual meetings, and phone conversations. The study will also be promoted through the AIHA's social media, website, conferences, support groups, virtual webinars, and other initiatives.

Inclusion/Exclusion Criteria

People of all ages with confirmed autoimmune hepatitis will be included in this study.

Enrollment

Approximately 500 people will be enrolled in this study in one of several ways, including in-person recruitment, through involvement in a prior research study, or through advertisements emailed to the AIHA's member list, posted on the AIHA's social media or website, or shared through its webinars, conferences, support groups, or educational initiatives.

Study Procedures

Informed consent will be obtained either in person, over the telephone, or electronically with approved study coordinator. Informed consent is available to be provided in English and Spanish. After consenting to participate in the study, patients will be asked to provide their primary treating doctor's information (name, address) as well as their current pharmacy (name, address). Participants will then be provided with a dedicated link to the patient REDCap registry. Here, participants will provide demographic and health-related information relating to the timing of their AIH diagnosis, current and past treatments and medications, and most recent liver biopsy findings. They will complete several health-related quality of life questionnaires at regular intervals and will be asked to provide a 5mL saliva sample.

The study coordinator will complete and submit a physician certification letter to their treating practitioner for certification of disease diagnosis. Participants' medications will be collected from a list of current medications from their pharmacy. All of this information will be added to the study database in REDCap and will be retained indefinitely.

Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others and Risks of Study Participation

There is no anticipation of adverse events associated with participation in this minimal risk study. Nonetheless, all adverse events and unanticipated problems will be reported in accordance with federal, state, local and university guidelines.

Risks of study participation include the possibility of loss of confidentiality. Also, participants may be uncomfortable with the questions asked.

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Autoimmune Hepatitis Association Patient Registry

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions that might help change or improve the way we do things in the future.

This consent and authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form and ask any questions you have before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

Autoimmune hepatitis (AIH) is liver inflammation that occurs when the body's immune system attacks liver cells. It is caused by an overactive immune system, and it is unknown why this happens. The Autoimmune Hepatitis Association (AIHA) is a not-for-profit organization seeking to develop a patient registry for people who are affected by autoimmune hepatitis to begin to characterize this poorly understood disease.

We are asking you if you want to be in this study because you have self-identified as a person who has been diagnosed with AIH.

The study is being conducted by Craig Lammert on behalf of the AIHA. Dr. Lammert is a Hepatologist (liver doctor) with the Division of Gastroenterology at the Indiana University School of Medicine. The study is funded and supported by the AIHA with a grant from the Smith-Fuqua Foundation.

WHAT WILL HAPPEN DURING THE STUDY?

This is a patient registry study, which means that information is collected about and from you through questionnaires that request demographic and health-related data, such as diagnosis details, medications, treatments, and liver biopsy results. This information is put into a secure database.

You will be asked for a list of the current and past medications used in the treatment of your AIH and other medications currently used for other conditions. In the event you are unclear about your medications, you agree to allow the AIHA to obtain a list of current medications from your pharmacy (ies). You will complete several health-related quality of life surveys at regular intervals. You will be asked to provide about 5mL of saliva by spitting into a tube. Finally, you agree to allow the AIHA to submit a physician certification letter to your treating providers for certification of your disease process.

The information collected in this study will stay in the database indefinitely unless you tell us to remove it. Several times each year you will receive a link via email asking you to complete one or more of the questionnaires.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

You may be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer. You may feel uncomfortable spitting into a cup and can stop providing saliva at any time. Also, there is a risk

someone outside the study team could get access to your research or medical information from this study. More information about how we will protect your information to reduce this risk is below.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?
We do not think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other patients with AIH in the future.

Specimens collected from you for this research may be used to develop products which could be sold in the future. The investigator does not plan to share any profits or losses from the sale of those products with you.

WHAT WILL YOU DO WITH MY GENETIC INFORMATION
This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and to discriminate against you based on your genetic information.

Because you are agreeing to allow us to collect your samples for research that will be completed in the future, we do not know for sure all the ways that the specimens may be used. One of the ways we may use the specimens collected as a part of this study is for whole genome sequencing, which involves mapping all of our DNA. DNA contains the code that identifies you as a person and can be extracted from these samples. If we utilize your DNA, you should realize that every person's DNA is unique; therefore, it may be possible some day in the future that someone could find out who you are just from knowing your DNA sequence. Although there can be no absolute guarantee of security, every precaution will be taken to ensure that your samples and personal health information are maintained in a highly secure place and that no unauthorized person has access to your information. We hope to use your samples to develop new ways to diagnose and treat people with liver disease.

WILL I BE PAID FOR PARTICIPATION?
You will not be paid for participating in this study; however, we will provide an AIHA T-shirt to all participants in the US who successfully complete the questionnaires.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION AND SPECIMENS BE USED?
The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include making certain you meet the criteria to be in this study, gathering information about your medical history to include in the research data, reviewing results of your medical tests, checking on your health in the future to help answer our research question, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include information relating to your diagnosis, care and treatment of your liver disease and associated conditions.

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians [include specialty]
- IUMG – Primary Care Physicians
- Eskenazi Health
- Indiana Network for Patient Care (INPC)
- Health care organization(s) or provider(s) not listed above
- Other:

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- The following research sponsors: the AIHA and its designees or successors

Information and specimens collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. All samples and clinical and demographic data added to the study database will be de-identified, which means that identifying information such as name, social security number, address and full date of birth will be removed. Coded data linked to the sample will be kept on a secure computer that can only be accessed by authorized individuals.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Dr. Craig Lammert, at 317-278-1630. After business hours, please call 317-944-5000 and ask the operator to page Dr. Lammert.

In the event of an emergency, please call 317-944-5000, and ask the operator to page the Liver Fellow on call.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please call Dr. Lammert at 317-278-1630.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Craig Lammert, 702 Rotary Circle, Suite 225, Indianapolis, IN 46202. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

Agreement to be Contacted by Text and/or Email

We would like to communicate with you about this study by text message and/or email. We might use text or email to send you reminders about upcoming visits or appointments, check on how you are doing, or tell you about the progress of the research.

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, such as protected health information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____ I authorize the researchers to send me emails related to this research study
Email address for this communication: _____

_____ I authorize the researchers to send me text messages related to this research study
Phone number for this communication: _____

You can still participate in this study even if you do not want us to contact you by text or email.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name: _____

Participant's Signature:_____**Date:**_____

Participant's Address:_____

FOR RESEARCH INVOLVING CHILDREN, USE THE FOLLOWNING SIGNATURE BLOCKS, AS APPLICABLE

Printed Name of Child:_____

Child's Address:_____

Printed Name of Parent:_____

Signature of Parent:_____**Date:**_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date:**_____