OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: __16357_

Project Title:

Hepatitis C Treatment in PWIDs: MAT or Syringe Exchange Assisted-therapy vs Standard of Care

NCT Number:

NCT03093415

Last Review/Edits:

January 20, 2019

Research Consent Summary

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

Some parts of the study are optional. You may participate in the main study without participating in the optional parts.

1. The purpose of this study is to learn more effective ways to treat people living with both hepatitis C and a substance abuse disorder.
2. We hope that we can show that:
    a. by asking participants about their experience with addiction and hepatitis c, they can teach us new and innovative ways to treat this terrible virus.
    b. we can treat hepatitis C in participants suffering from substance abuse in the safety net clinic setting as, or more effectively as referring to specialty treatment center.
    c. a substance abuse disorder diagnosis should not prevent access to treatment of hepatitis C.
    d. the risk of hepatitis C reinfection in people who inject drugs is low under appropriate medical care.
3. Merck & Co., Inc. is paying for the research study.
4. Everyone who joins the study will participate in surveys and in depth interviews. Participants will be provided with the FDA approved hepatitis C treatment, Zepetier™ (known as “the study drug” in the rest of this form), and all screening labs, at no charge.
5. If you join the study, you will have ten visits over 18 months, and you will be taking medicine for 12 weeks of this time. We will also ask you to fill out surveys and participate in one or more interviews during the initial visits to help us better understand how to support you through treatment and improve the care of our participants with hepatitis C.
6. Your medical record will be reviewed and collected for your medical diagnoses, blood tests and imaging study results, and liver biopsy and/or FibroScan result.
7. Some of the survey and interview questions may seem personal and may upset you. You may refuse to answer any of the questions that you do not wish to answer. There is minimal risk of breach of confidentiality
8. The in-depth personal interviews are optional. You may decide not to participate in these portions if you do not wish to. You will be asked separate permission prior to any of the optional portions of the study.
9. If you agree to participate in this study, the information collected may be stored, separate from your personal identifiers, for an indefinite period of time for future research, including possible evaluation for risk of repeat infection. Use of your study information for future study is optional.

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Research Consent and Authorization Form

TITLE: A prospective cohort study comparing the effectiveness of Zepatier for the treatment of hepatitis C in an academic center population to people who inject drugs (PWIDs) in a safeteny net clinic setting engaged in either Medication Assisted Therapy or syringe exchange program.

PRINCIPAL INVESTIGATOR: Dr. Atif Zaman, 503-494-8071

Co-Investigators:

Dr. Andrew Seaman, 971-271-6102
Dr. Ryan Hutchinson, 503-535-3800

FUNDED BY: Merck & Co.

SUPPORTED BY: OHSU, Central City Concern, and Outside In Clinic

CONFLICT OF INTEREST: The primary investigators currently have no conflicts of interest.
The lead primary investigator will not receive any compensation for this study.
The co-investigators will receive a total of 5% of their salaries from the research grant from Merck & Co.

PURPOSE:
You have been invited to be in this research study because you have hepatitis C virus (HCV) infection, wish to proceed with treatment but are unable to access it due to current insurance restrictions. The purpose of this study is to learn more effective ways to treat people living with both hepatitis C and a substance abuse disorder, in the community setting.

This study will be conducted at Old Town Clinic and Outside In; both are safety net clinics in the downtown Portland area. Approximately 25 people will be enrolled at each of these sites.

There will be a total of 50 participants in this part of the study. The study will require 10 clinic visits over 18 months.

We are asking you to provide information for a data bank, also called a repository. This information will be stored indefinitely and may be used and disclosed in the future for research.

PROCEDURES:

1) Surveys. You will be asked to complete a total of three separate surveys. You will take these surveys during your first visit in the program and again in the last encounter. We expect these surveys to take between 15 and 25 minutes.

2) Interview (optional). We may also invite you to be interviewed at any of these time points; this portion of the study is optional. You will be asked questions about your social support, how you feel about your hepatitis C, some basic information about your background (such as your age and ethnicity, for example), and what ideas you have about what we can do to make your treatment most successful. This optional portion of the study will take between 60 and 90 minutes, for which you will be compensated. Your medical record at your current primary care office, Old Town Clinic or Outside In, will be reviewed and collected for your medical diagnoses, blood tests and imaging study results, and liver biopsy and/or FibroScan result.

We do not plan to share the results of surveys and interviews with you, though the published results of the study can be made available to you on request. If we discover information that is important for your health care, either in this study or in the future, we will contact you and ask if you want to know the results. You may learn information about your health that is upsetting.

3) Lab Tests and Imaging. If your primary care provider or clinic hepatitis C provider feels it is indicated, you will be asked to have labs drawn to help them better treat your hepatitis C. You may also be asked to do a liver test called a fibroscan, which uses an ultrasound to see how much damage the hepatitis C has caused to your liver. These results will be shared with you as it is a part of your normal medical care.

4) Treatment. If you enter the study and meet national guidelines for treatment of your hepatitis C, the study drug will be started at the recommended dose for a total of 12 weeks.

RISKS AND DISCOMFORTS:

1) Surveys and Interviews. Some of the questions in the surveys or interviews may seem personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

2) Lab Tests and Images. We will draw blood from a vein in your arm. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting. Some participants with a history of injection drug use may find the needles involved triggering. The fibroscan imaging is not thought to cause discomfort and is without known health risks.

3) Treatment. About 1/100 people experience a temporary increase in their liver test called ALT to about 5 times the upper limit of normal. This typically resolves when you finish treatment. In previous studies, about 1/10 participants experienced headaches and fatigue during treatment. However, this is about the same number of participants with headache and fatigue that received a false pill called placebo, and so these side effects may not have been caused by the drug. In one study, participants on the study drug were slightly more likely to have nausea than participants on the placebo (false pill). The study drug can interact with some other medications. Your provider and pharmacist will look for all these interactions and make adjustments as necessary and as agreed upon by you.

BENEFITS:
You may or may not personally benefit from being in this study. . However, by serving as a subject, you may help us learn how to benefit patients in the future.

ALTERNATIVES:
You may choose not to be in this study.

CONFIDENTIALITY:
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Confidentiality will be protected by (a) assigning you a code number, (b) identifying surveys and interview transcript by code number and not name, (c) changing any identifiable information in the transcripts with synonyms and (d) storing the data obtained from completed surveys, transcripts, medical record reviews, and demographic data on a secure computer with a restricted password.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository, and conduct future research. The storage in a repository and future use of your information is optional. The stored data will be without identifiers and only released as requested.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, Merck and Co.
- The Office for Human Research Protections, a federal agency that oversees research involving humans.

Those listed above may also be permitted to review and copy your records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

The law provides additional confidentiality protection for certain types of information, including drug and alcohol addiction, treatment, or referral information, as well as mental health records. We will collect basic information regarding your active or former substance use. We may disclose this information, separated from patient identifiers, until the study has ended. This will enable us to better understand how to treat you for your hepatitis C, as well as treat people in the future who also suffer from substance abuse disorders. We may access this information in the future to investigate risk of re-infection of hepatitis C due to resumption of risk behavior, such as injection with used needles.

When we send information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your

permission.

Data from this study may be shared with other investigators for future research studies. All identifying information about you will be removed from the data before they are released to any other investigators.

We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

COMMERCIAL DEVELOPMENT:
Samples and information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

COSTS:
Some of the services or items in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these services or items will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

You will be compensated for all components of the study felt to be outside the scope of routine medical care. This includes two separate survey sessions and one in-depth interview session. For each of these sessions you will be compensated with one $15 Fred Meyer Gift Card.

LIABILITY:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Dr. Atif Zaman at 503-494-8071.

If you are injured or harmed by the study procedures you will be treated. OHSU, Outside In, Old Town Clinic, and the funder do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503)

494-7887.

PARTICIPATION:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact Dr. Atif Zaman at 503-494-8071, Old Town Clinic co-Investigator Andrew Seaman at (971) 271.6102, or Outside In co-Investigator at 503-535-3800.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- ¥ Your questions, concerns, or complaints are not being answered by the research team.
- ¥ You want to talk to someone besides the research team.
- ¥ You have questions about your rights as a research subject.
- ¥ You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. Some parts of the study are optional. You can choose not to participate in some or all of the optional parts but still participate in the rest of the study.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. Talk to the investigator if you want to withdraw from the study. You can choose to withdraw from some or all of the optional parts of this study without withdrawing from the whole study. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study or change which parts of the study you are participating in.

If you choose to withdraw from the study, we will ask you to participate in one additional visit with your provider to ensure you get the best possible treatment of your condition. At that time, we will destroy all the information collected during the study, including the paper and electronic versions. Your information will not be available for future research.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Attention: Dr. Andrew Seaman, Hepatitis C Study Coordinator, 727 W Burnside, Portland, OR, 97209. 971-271-6103 / seaman@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

You may be removed from the study if the investigator stops the study.
We will give you any new information during the course of this research study that might change the way you feel about being in the study.

The information that we will collect from you will be stored separately from your name or any other identifier. We will be able to use this information to destroy your information should you chose to withdraw from study at any time in the future. Only three doctors, Dr. Zaman at OHSU, Dr. Seaman at Old Town Clinic, and Dr. Hutchison at Outside In will have access to personally identifiable information. If you choose to allow your information to be used for future research, this information will only be made available separate from your name or personal identifiers.

PARTICIPANT OPTIONS

The optional portions of this study are described in detail throughout this consent form and listed here as a summary. Please read the options and place your initials next to your choices. You can still participate in the main part of the study even if you choose not to participate in the optional parts.

_____ I give my consent to participate in the optional interview portion of the study and will accept the compensation of a $15 Fred Meyer gift card for doing so.

_____ I give my consent for my information to be stored for future research.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

_____	_____	_____
Subject Printed Name	Subject Signature	Date

_____	_____	_____
Person Obtaining Consent, Printed Name	Consenter Signature	Date