ACTG A5380
Clinician Summary Sheet

Title of Study: Glecaprevir/pibrentasvir Fixed-dose Combination Treatment for Acute Hepatitis C Virus Infection (PURGE-C)

Principal Investigator: Jorge L. Santana Bagur, MD, FIDSA

Brief Description: This is a phase II single-arm, open-label study to assess the efficacy of a fixed dose combination (FDC) of glecaprevir/pibrentasvir (G/P) in acute hepatitis C (HCV)-infected participants, with or without HIV-1 coinfection, given for 4 weeks. This study will enroll participants with acute HCV-infection at US and select non-US sites. The study has two steps: Step 1- Four weeks of treatment for acute infection and up to 24 weeks of follow-up. Participants with recurrence or virologic failure will be eligible for re-treatment (Step 2). Step 2: Re-treatment will be with G/P with or without ribavirin (RBV) for up to 16 weeks.
NOTE: Alterations in the re-treatment regimen for relapses and virologic failures are permitted at the discretion of the site PI and with A5380 core team approval.

Purpose of this study: Recently, incidence of acute HCV has been rising, with the Centers for Disease Control and Prevention (CDC) estimating that there are about 30,000 new cases of acute HCV per year, with a range of 24,200-104,200 cases. For a variety of reasons, only a fraction of persons with acute HCV are reported to public health authorities. Early identification of acute HCV infection is essential to provide preventive counseling and, if necessary, curative treatment to clear virus and prevent onward transmission. Models suggest that clearance of HCV among high-risk individuals may reduce overall prevalence and incidence, despite risks for re-infection.

This study will evaluate acute HCV treatment response to G/P given for 4 weeks as assessed by sustained virologic response 12 weeks post-treatment (SVR12, defined as HCV RNA <lower limit of quantification, target detected or target not detected). The study will also evaluate the safety and tolerability of combination oral antiviral therapy with G/P given for 4 weeks in persons with acute HCV-infection, regardless of genotype and HIV status.

Requirements to Enter Study:

- Age ≥18 years of age
- Mono or Co-infected
- Documentation of acute HCV infection
- If HIV positive, ARV untreated due to lack of indication per provider or on a stable antiretroviral regimen
- If HIV positive, HIV RNA <50 and CD4 >100, if on ART
- Must agree not to participate in a conception process
- HCV treatment naïve during current acute HCV infection
- Non-cirrhotic with no other chronic liver disease
- Hepatitis A and B negative
- Not pregnant or breastfeeding

Treatment: Glecaprevir/pibrentasvir Fixed-dose Combination daily for 4 weeks. Those who have recurrence or virologic failure after 4 weeks will receive retreatment of G/P with or without RBV for up to 16 weeks.

Duration: Up to 28 weeks on Step 1, up to an additional 40 weeks if participant enters Step 2

Contact Information:
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Aprobado por el MSC-IRB
CEE-SA-2020-4793

ACTG A5380
Participant Summary Sheet

Title of Study: Glecaprevir/pibrentasvir Fixed-dose Combination Treatment for Acute Hepatitis C Virus Infection (PURGE-C)

Principal Investigator: Jorge L. Santana Bagur, MD, FIDSA

Brief Description: This is a study to treat participants, with or without HIV, who are found to have been recently infected with the Hepatitis C virus (HCV). This known as acute HCV.

Purpose of this Study: People who are recently infected with HCV are often considered to have acute HCV. People with acute HCV have a good chance of being cured of the infection when they are treated with a combination of two drugs within the first 6 months of being infected. This study is being done to see if a shorter course of treatment will be effective if started early in the infection (Step 1). In case of failure with this shorter course of treatment, a longer and different treatment regimen for HCV will be offered (Step 2).

Requirements to Enter Study:

- Age ≥18 years of age
- With or without HIV. If living with HIV, on a stable antiretroviral regimen or untreated due to lack of indication per physician.
- HIV RNA <50 and CD4 >100
- May not have Hepatitis A or B
- Recently infected with HCV
- Cannot be pregnant or breastfeeding
- Must be willing to use birth control to prevent pregnancy
- Must be willing to come to study visits
- Must be able to swallow pills
- May not have other known liver disease

Study Drugs: Glecaprevir/pibrentasvir (G/P) Fixed-dose Combination (FDC) three pills by mouth once a day for 4 weeks (Step 1). If this medicine does not work for you after the 4 weeks or you become infected again while on study, you will be asked to take the G/P with or without Ribavirin for a longer time, 8-16 weeks longer.

Duration of Study: Up to 28 weeks on Step 1 and up to an additional 40 weeks if on Step 2.

For more information contact:

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MSC-IRB Approval
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ACTG A5380
Hoja de Resumen del Participante

Título del Estudio: Tratamiento con una Dosis Fija Combinada de Glecaprevir/Pibrentasvir para la Infección Aguda con el Virus de la Hepatitis C (PURGE-C)

Investigador Principal: Jorge L. Santana Bagur, MD, FIDSA

Descripción Breve: Este es un estudio para tratar a los participantes, con o sin VIH, que han sido recientemente infectados con el virus de la hepatitis C (VHC). Esto se conoce como VHC agudo.

Propósito del Estudio: Las personas recientemente infectadas con el VHC a menudo se consideran que tienen VHC agudo. Las personas con VHC agudo tienen una buena probabilidad de curarse de la infección cuando son tratadas con una combinación de dos medicamentos dentro de los primeros 6 meses de haberse infectado. Este estudio se está haciendo para ver si un curso más corto de tratamiento será efectivo si se comienza temprano en la infección (Paso 1). En caso de fracaso con este curso de tratamiento más corto, se ofrecerá un régimen de tratamiento más largo y diferente para el VHC (Paso 2).

Requisitos clave para ingresar al estudio:

- Edad ≥18 años de edad
- Con o sin VIH. Si vive con VIH, en un régimen antirretroviral estable o sin tratamiento debido a la falta de indicación por médico.
- ARN del VIH <50 y CD4> 100
- No puede tener hepatitis A o B
- Recientemente infectado con VHC
- No puede estar embarazada o amamantando
- Debe estar dispuesto a usar un método anticonceptivo para prevenir el embarazo.
- Debe estar dispuesto a asistir a visitas de estudio
- Debe poder tragar pastillas
- No puede tener otra enfermedad hepática conocida.

Tratamiento: Glecaprevir / pibrentasvir (G/P) Combinación de dosis fija (FDC) tres píldoras por vía oral una vez al día durante 4 semanas (Paso 1). Si este medicamento no funciona para usted después de las 4 semanas o si se infecta nuevamente durante el estudio, se le pedirá que tome el G/P con o sin Ribavirina por un tiempo más prolongado, 8-16 semanas más.

Duración del Estudio: Hasta 28 semanas en el Paso 1 y hasta 40 semanas adicionales en el Paso 2.

Para más información comuníquese con:

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¿Has sido diagnosticado con Hepatitis C recientemente?

Entonces puedes ser elegible a participar en este estudio clínico, donde buscamos saber si un ciclo más corto de medicamentos contra la hepatitis C, logrará una cura en personas recientemente infectadas con hepatitis C.

Aprobado por el MSC-IRB

Requisitos:

***Tener 18 años o más.**
***Puede estar viviendo con o sin VIH.**
***CD4 >100**
***No puede tener hepatitis A o B.**
***Recientemente infectado con VHC.**

Duración del estudio: 1 año.
Se proporcionará el medicamento del estudio.

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Su participación será compensada.

Informacion adicional: Daniel Casiano, RN
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