Trial record **1 of 787** for: heartland

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# A Study to Investigate HCV Response Rates in Real World Patients: HEARTLAND Study (HEARTLAND)



ClinicalTrials.gov Identifier: NCT03710252

Recruitment Status : Completed
First Posted : October 18, 2018
Last Update Posted : October 18, 2018

**Sponsor:**
American Research Corporation

**Collaborator:**
AbbVie

**Information provided by (Responsible Party):**
American Research Corporation

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

## Study Description

Go to

Brief Summary:
This is a Phase IV, open label, single center study of OBV/PTV/r + DSV +/- RBV for 12 or 24 weeks for the treatment of chronic HCV-1 infection in a real world urban clinical setting.

| Condition or disease | Intervention/treatment | Phase |
|---|---|---|

| | | |
|---|---|---|
| Chronic Hepatitis C | Drug: paritaprevir/ritonavir/ombitasvir + dasabuvir +/- ribavirin | Phase 4 |

Detailed Description:

This is a Phase IV, open label, single center study of OBV/PTV/r + DSV +/- RBV for 12 or 24 weeks for the treatment of chronic HCV-1 infection in a real world urban clinical setting.

The study will enroll chronically infected GT 1 patients who are treatment naïve or who have failed a regimen including pegIFN/RBV +/- telaprevir, boceprevir, or simeprevir.

In addition, up to 20 chronically infected GT1 patients who have traditionally been excluded from clinical trials due to mild to moderate renal insufficiency, irrespective of other co-morbid conditions including poorly controlled diabetes mellitus, high BMI, HIV infection will be enrolled.

## Study Design

Go to

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|---|---|
| Study Type : | Interventional (Clinical Trial) |
| Actual Enrollment : | 100 participants |
| Intervention Model: | Single Group Assignment |
| Intervention Model Description: | This is a Phase IV, open label, single arm study. |
| Masking: | None (Open Label) |
| Primary Purpose: | Treatment |
| Official Title: | A Study to Investigate HCV Response Rates in Real World Patients Traditionally Excluded From Clinical Trials: The **HEARTLAND** Study |
| Actual Study Start Date : | March 2016 |
| Actual Primary Completion Date : | September 2017 |
| Actual Study Completion Date : | September 2017 |

**Resource links provided by the National Library of Medicine**

Drug Information available for: Ribavirin Ritonavir

U.S. FDA Resources

## Arms and Interventions

Go to

| Arm | Intervention/treatment |
|---|---|
| Experimental: Single | Drug: paritaprevir/ritonavir/ombitasvir + dasabuvir +/- ribavirin |

| | |
|---|---|
| Ombitasvir/paritaprevir/ritonavir (OBV/PTV/r) + databuvir (DSV) +/- ribavirin (RBV) | OMB/PTV/r + DSV +/- RBV |

## Outcome Measures

Go to

Primary Outcome Measures :

1. The primary analysis will be sustained virologic response 12 weeks after the last treatment dose (SVR12) for the all treated population. [ Time Frame: 12 weeks after last treatment ]

   Primary Analysis

Secondary Outcome Measures :

1. Effect of baseline resistance variants on SVR12 (subgroups: all RAVs, different classes of RAVs) [ Time Frame: 12 weeks after last treatment ]

   Secondary Analysis

2. Evaluate patient reported outcomes via the SF36v2 survey (subgroups: those who achieve SVR12 and those who do not) [ Time Frame: 12 weeks after last treatment ]

   Secondary Analysis. Comparison between baseline and end of treatment

3. Evaluate patient adherence (subgroups: those who achieve SVR12 and those who do not) [ Time Frame: 12 weeks after last treatment ]

   Secondary Analysis

## Eligibility Criteria

Go to

**Information from the National Library of Medicine**

*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.*

| | |
|---|---|
| Ages Eligible for Study: | 18 Years and older (Adult, Older Adult) |
| Sexes Eligible for Study: | All |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

- Age ≥ 18 years
  - Patients must have chronic GT 1 HCV infection (GT1a, GT1b or GT1a/1b)
  - Patient and partner(s) must agree to use acceptable methods of contraception
  - Patient must be able to read and understand English and/or Spanish
  - Written informed consent

Exclusion Criteria:

- Currently taking or planning on taking any prohibited medications (see US PI)
  - Evidence of decompensated liver disease (Child-Pugh B or C) including the presence of clinical ascites, bleeding varices, or hepatic encephalopathy
  - Abnormal lab values, including:
    - Hemoglobin (Hgb) <8 g/dL
    - Platelets <25,000 cells/mm3
    - Absolute neutrophil count (ANC)<500 cells/mm3
    - Bilirubin >3
    - INR>2.3 ALT/AST > 10 x ULN
    - Serum albumin <2.8
    - GFR <30 mL
  - Alcohol use: >3 drinks per day consistently
  - Uncontrolled HIV or HBV coinfection

## Contacts and Locations

Go to

**Information from the National Library of Medicine**

*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number):*
***NCT03710252***

**Sponsors and Collaborators**

American Research Corporation

AbbVie

**Investigators**

Principal Investigator: Fred Poordad, MD American Research Corporation

## More Information

Go to

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|---|---|
| Responsible Party: | American Research Corporation |
| ClinicalTrials.gov Identifier: | NCT03710252 History of Changes |
| Other Study ID Numbers: | TLI_IIS_01_2015 |
| First Posted: | October 18, 2018 Key Record Dates |
| Last Update Posted: | October 18, 2018 |
| Last Verified: | October 2018 |

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Undecided

| | |
|---|---|
| Studies a U.S. FDA-regulated Drug Product: | No |
| Studies a U.S. FDA-regulated Device Product: | No |
| Product Manufactured in and Exported from the U.S.: | No |

Additional relevant MeSH terms:

Hepatitis C
Hepatitis, Chronic
Hepatitis C, Chronic
Hepatitis, Viral, Human
Virus Diseases
Flaviviridae Infections
RNA Virus Infections
Hepatitis
Liver Diseases
Digestive System Diseases
Ribavirin
Ritonavir
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antiviral Agents
Anti-Infective Agents
HIV Protease Inhibitors
Protease Inhibitors
Enzyme Inhibitors
Anti-HIV Agents
Anti-Retroviral Agents
Cytochrome P-450 CYP3A Inhibitors
Cytochrome P-450 Enzyme Inhibitors