

*2024 Virtual Conference*

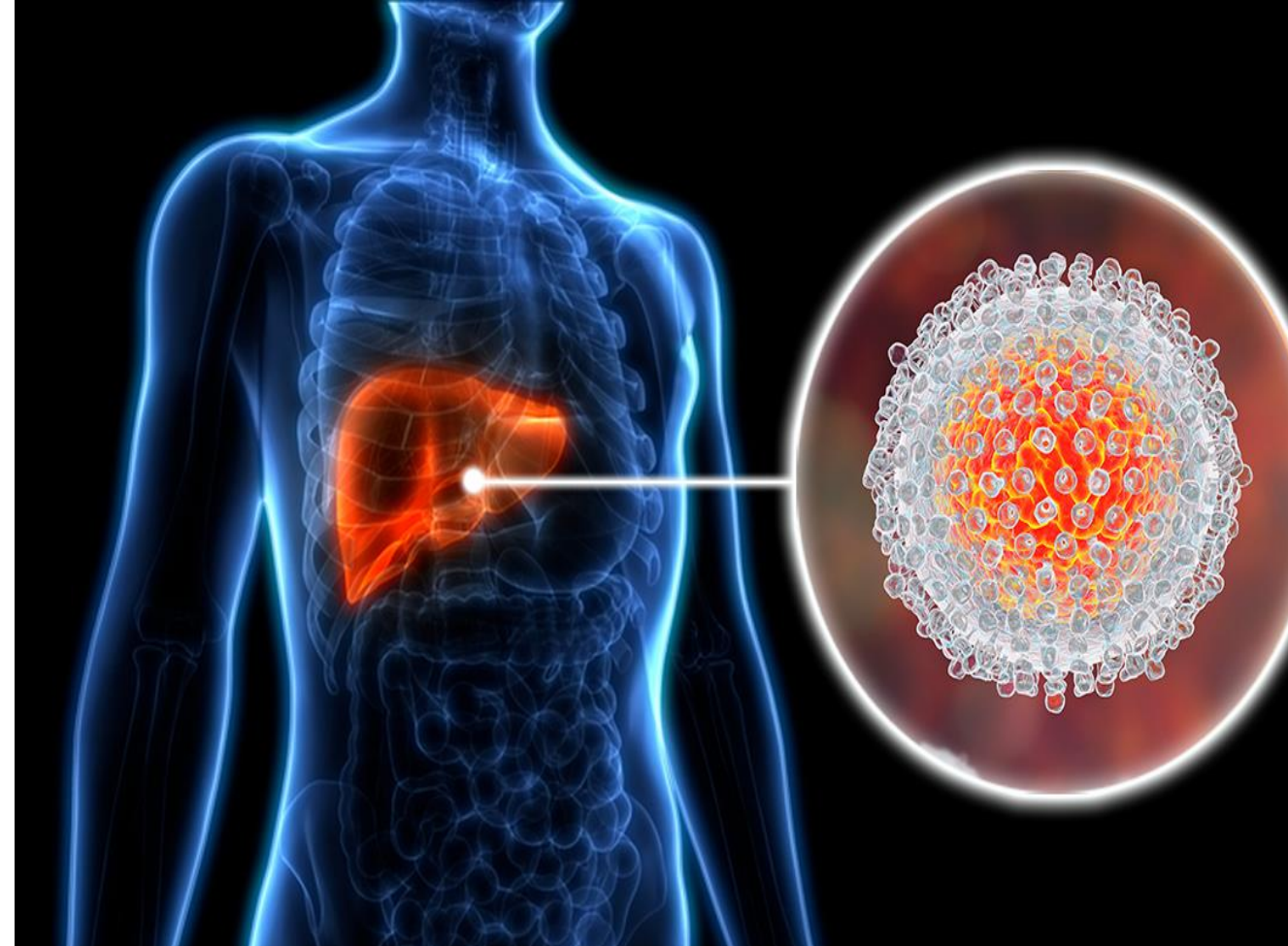
# Hepatitis C in Neonates and People of Childbearing Potential

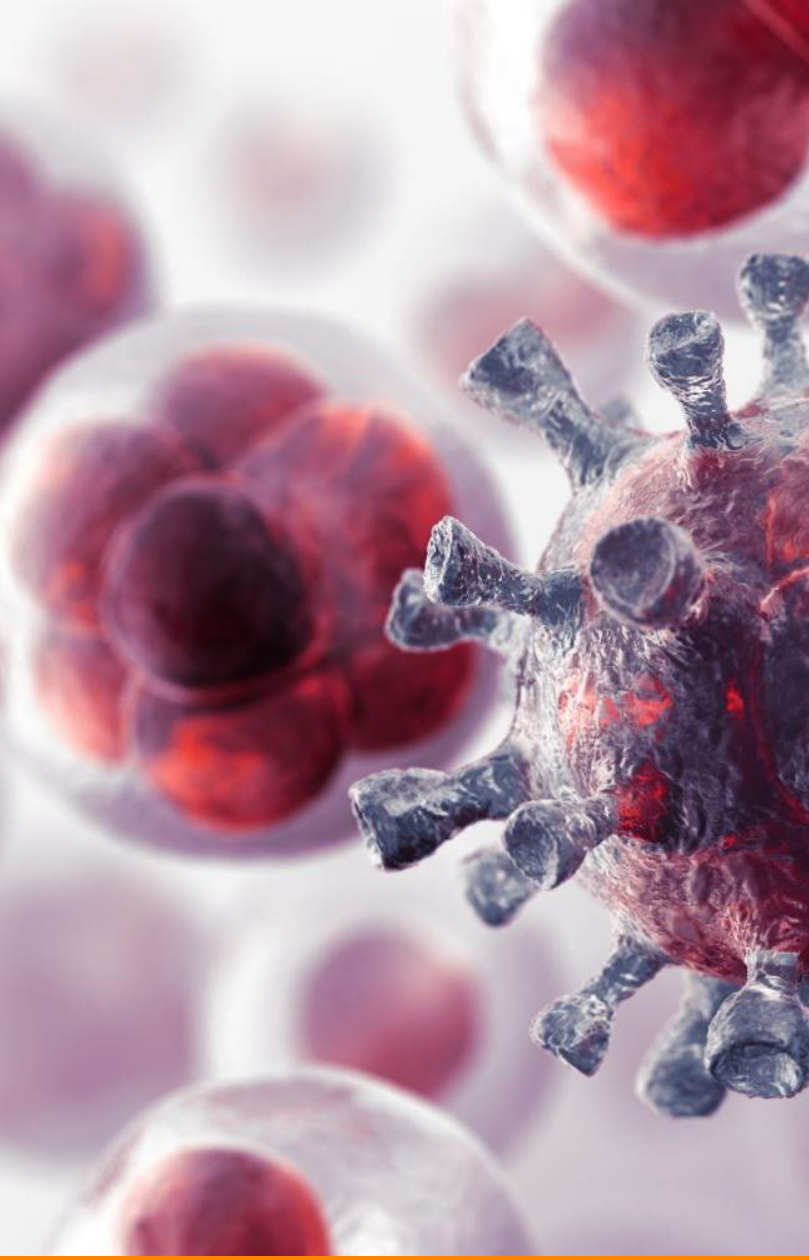
Taylor Maddox-Rooper, MS

# What is Hepatitis C?

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- Hepatitis C (HCV) is an inflammatory virus that affects the liver
- There are six different genotypes of the HCV virus
- By current estimation, 50 million people have a chronic Hepatitis C infection
- The World Health Organization estimates that in 2022 242,000 died from Hepatitis C complications





# Why is Hepatitis C so dangerous?

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- There is currently no vaccine to prevent Hepatitis C
- Infection with Hepatitis C can be life-threatening
- Hepatitis C infection occurs in all regions of the world
- 30% of Hepatitis C infections are acute with the virus clearing within 6 months of infection. The remaining 70% of infections will become chronic
- Most people once they become infected have no symptoms initially

# Who is at risk of Hepatitis C?



# What are the symptoms of a Hepatitis C infection?

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- Fever
- Fatigue
- Dark urine
- Joint Pain
- Jaundice
- Bruising easily
- Loss of appetite
- Nausea and vomiting
- Abdominal pain
- Pale or clay-colored stools
- Itching

# How do you get Hepatitis C?

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Hepatitis C (HCV) can be contracted through the sharing of or contact with blood or blood products that is infected with the virus

## Examples of transmission:

- Sexual contact
- Passed from a Hep C-positive mother to child at birth
- Sharing personal items (i.e. toothbrush, razor, nail clippers)
- Tattooing or body piercings
- Sharing of needles/syringes
- Transfusions of unscreened blood
- Inadequate sterilization of medical equipment

# How do you test for Hep C?

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- Most people do not get tested until years after infection due to the infection being asymptomatic
- Testing for anti-HCV antibodies identifies infected persons
- If positive for anti-HCV antibodies, an RNA test is performed to confirm chronic infection and if treatment is needed
- If a person has tested positive for a chronic infection further testing should be done to determine the degree of liver damage if there is a development of cirrhosis, fibrosis, or cancer





# Hepatitis C in Pregnancy

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- Infants born to Hep C mothers have a 4-7% chance of a perinatal HCV infection
- Infants born to Hep C mothers have an increased risk of congenital anomalies, low birth weight, and Neonatal Intensive Care Unit admissions (NICU)
- Hep C-exposed infants are at increased risk of an adverse neurologic outcome
- Currently there is no approved treatment for Hep C during pregnancy



# Hepatitis C in Children

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- In the US approximately 250,000 children have a Hep C infection
- Children who are infected with Hep C can clear the virus from the body within the first two years of life
- Similarly to adults the virus can be detected at the earliest around 2 weeks after contracting the infection
- The average incubation period is 6 to 9 weeks after initial exposure
- Like with adults not every child will have symptoms
- The American College of Pediatrics recommends testing for Hepatitis C for children born to Hep C positive mothers at 18 months of age

# Hepatitis C symptoms in children

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- Loss of appetite
- Tiredness
- Jaundice
- Fever
- GI issues like diarrhea and stomachache
- Light-colored stools
- Dark urine

# Can you treat Hep C?




**YES!**

- There are several options for curing Hepatitis C
- Some medications like Harvoni will only treat certain genotypes
- While other medications like Epclusa can treat all genotypes
- Several of these medications are approved for use in HCV treatment in children
- There is not currently an FDA-approved medication for HCV treatment in pregnancy

# Research is currently being done on Hep C treatment in Pregnancy

**ClinicalTrials.gov**  
Find Studies ▾ Study Basics ▾ Submit Studies ▾ Data and API ▾ Policy ▾ About ▾ My Saved Studies (0) →

Home > Search Results

 **The U.S. government does not review or approve the safety and science of all studies listed on this website.**  
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Focus Your Search (all filters optional)

- Phase 1 (0)
- Phase 2 (0)
- Phase 3 (0)
- Phase 4 (0)
- Not applicable (0)

Study Type

- Interventional (60)
- Observational (30)
  - Patient registries (3)
  - Expanded access (0)
  - Individual patients (0)

Clear Filters (4) Apply Filters

Search Results

Viewing 1-10 out of 30 studies

Showing results for: **hepatitis C** | Other terms: pregnancy | Adult (18 - 64) | Observational studies

+ [Synonyms of conditions or disease \(8\)](#)

Sort studies by Newest First

None Selected [Download] [Bookmark] [RSS] [Previous] [Next] [Manage]

<input type="checkbox"/>	Study Title	NCT Number	Status	Conditions	Interventions
<input type="checkbox"/> 1	<a href="#">Feasibility and Acceptability of HCV Treatment in Pregnancy</a>	NCT06367465	Recruiting	<ul style="list-style-type: none"><li>Hepatitis C</li><li>Pregnancy Complications</li></ul>	<ul style="list-style-type: none"><li>Drug: Glecaprevir-pibrent</li></ul>
<input type="checkbox"/> 2	<a href="#">Observational Study of the Interaction Between Hepatitis C Virus Infection and Pregnancy</a>	NCT05929963	Enrolling by invitation	<ul style="list-style-type: none"><li>Hepacivirus</li><li>Pregnancy</li></ul>	<ul style="list-style-type: none"><li>Other: HCV infection stat</li></ul>
<input type="checkbox"/>	<a href="#">Health and Migration Trajectory</a>	NCT05472051	Completed	<ul style="list-style-type: none"><li>HIV Infections</li></ul>	<ul style="list-style-type: none"><li>Other: Community-based</li></ul>

# Research is currently being done on Hep C treatment in Pregnancy



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**Focus Your Search** (all filters optional) Hide

**Condition/disease**

**Other terms**

**Intervention/treatment**

**Location**  
Search by address, city, state, or country and select from the dropdown list

**Study Status**

**Looking for participants**

Not yet recruiting (0)

Recruiting (2)

**Search Results**

Viewing 1-2 out of 2 studies

Showing results for: **hepatitis C** | Other terms: pregnancy | Not yet recruiting, Recruiting studies | Adult (18 - 64) | Interventional studies

[+ Synonyms of conditions or disease \(8\)](#)

Sort studies by

None Selected

<input type="checkbox"/>	Study Title	NCT Number	Status	Conditions	Interventions
<input checked="" type="checkbox"/> 1	<a href="#">Sofosbuvir/Velpatasvir Treatment of Chronic Hepatitis C During Pregnancy</a>	NCT05140941	Recruiting	<ul style="list-style-type: none"><li>Hepatitis C, Chronic</li><li>Pregnancy; Infection</li></ul>	<ul style="list-style-type: none"><li>Drug: Sofosbuvir/Velpatasvir Oral Tablet</li></ul>
<input type="checkbox"/> 2	<a href="#">A Trial of Transplanting Hepatitis C Kidneys Into Hepatitis C-Negative Kidney Recipients</a>	NCT04075916	Recruiting	<ul style="list-style-type: none"><li>End Stage Renal Disease</li></ul>	<ul style="list-style-type: none"><li>Drug: Epluse</li></ul>

10 studies per page

# STORC Trial for Hepatitis C treatment in Pregnancy

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- Marshall's Division of Addiction Sciences was recently initiated to participate in the STORC trial.
- This interventional study looks at the medication Epclusa (sofosbuvir/velpatavir) in pregnant persons.
- This is a chance at a cure for a disease that pregnant people will not otherwise have access to.

# STORC Trial for Hepatitis C Treatment in Pregnancy

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- STORC like all studies are voluntary and the participants can leave at any time with no penalties.
- The study pays for the medication, there is no cost to the participants.
- They can continue their care at their normal obstetrician's office.
- Monthly visits
- As part of the study protocol the mother will be tested multiple times to monitor her viral load during study participation, this can help determine the change of perinatal transmission.
- As part of the study protocol the infant being born to a Hepatitis C-positive mother will receive testing for Hep C at approximately 8 weeks, 6 months, and 12 months of age.

# STORC Trial for Hepatitis C Treatment in Pregnancy

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## Inclusion criteria:

- 18 to 45 years old
- HCV positive
- Singleton pregnancy 12 w 0d to 29 w 6d
- Hepatitis B negative
- If living with HIV must be on antiretroviral therapy
- If taking acid suppressant medication, be able to follow specific dosing instructions

## Exclusion criteria:

- Cannot plan to relocate away from the area for the next 16 months
- Cannot have a documented history of cirrhosis
- Cannot be currently enrolled in another investigational clinical trial
- Cannot have any known fetal chromosome abnormalities
- Cannot have clinically significant and habitual non-therapeutic drug use (not including marijuana)



# Content References

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- [https://www.chop.edu/conditions-diseases/hepatitis-c?utm\\_source=google&utm\\_medium=cpc&utm\\_campaign=gastroenterology&utm\\_content=hepatitis-hepatitis\\_c-consumer-conversion-us&gclid=EAlaIQobChMI3bKAmda9iAMVDI1HAR28VgSuEAAYASAAEglikfD\\_BwE](https://www.chop.edu/conditions-diseases/hepatitis-c?utm_source=google&utm_medium=cpc&utm_campaign=gastroenterology&utm_content=hepatitis-hepatitis_c-consumer-conversion-us&gclid=EAlaIQobChMI3bKAmda9iAMVDI1HAR28VgSuEAAYASAAEglikfD_BwE)
- <https://www.cdc.gov/mmwr/volumes/72/rr/rr7204a1.htm>

# Links for Pictures

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- <https://www.cdc.gov/hepatitis-c/index.html>
- <https://www.gettyimages.com/photos/large-group-of-people>
- <https://dressalab.com/products/hcv-rna-pcr-quantitative?variant=42300187607209>
- <https://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html>
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- <https://health.clevelandclinic.org/pregnancy-glow>
- <https://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html>
- <https://clinicaltrials.gov/>
- <https://www.etsy.com/listing/1593544340/stork-baby-clipart-delightful-stork-baby>

# Marshall Addiction Sciences Research Team for STORC

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- PI: Todd Davies, PhD
- Lead Medical Clinician: Zachary Hansen, MD
- Lead Pharmacist: Ron Carico, PharmD
- Lead Coordinator: Taylor Maddox-Rooper, MS
- Obstetrician: Adam Franks, MD
- Alternate Coordinator: Mary Edwards, MS
- Alternate Coordinator/ Lead internal monitor: Lacey Andrews, MS, CCRC, CCRA
- Alternate Medical clinicians: Jeremy Mount APRN and Dathan Jobe APRN
- Consulting Hepatologist: Tejas Joshi, MD

**If you have any patients who may benefit from this study, please contact our lead coordinator**

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# Thank you!

