HCV

An Observational Study of Hepatitis C Virus in Pregnancy

Objective: To identify risk factors associated with mother to child transmission of HCV.
Project Status: Currently screening

Clinical Centers: All current centers

Design Type: Observational Cohort Study

Major Eligibility Criteria:

- Singleton gestation
- An HCV antibody positive screen OR a randomly selected HCV antibody negative screen matched to a control patient by project gestational age +/- 2 weeks and clinical center site.
- Gestational age at screening no later than 23^6 weeks, gestational age at enrollment no later than 27^6 weeks

Groups:

- Cases: HCV antibody positive
- Controls: HCV antibody negative. Two randomly-selected controls per case.

Sample Size: Cases 1,800. Controls 3,600.

Scheduled Evaluations / Data Collection:
Maternal Visits at Baseline, 24-28 weeks gestation, and 32-36 weeks gestation

Delivery:

- Delivery and neonatal data
- Infant visits at 2 and 18 months

Management Protocol:

Outcome Measures:

Primary:

- HCV infection of the offspring, where infection is defined as:
  - HCV RNA positive by PCR at the 2-month visit
  - HCV RNA positive and HCV antibody positive at the 18- month visit
  - HCV PCR positive at the 18- month visit with a negative HCV antibody at the 18- month visit and negative HCV RNA at the 2-month visit. (However, the positive result must be confirmed by a repeat test on the 18-month sample to qualify.)

- HCV antibody positive at the18- month visit with negative HCV RNA at both visits. (However, the positive result must be confirmed by a repeat test on the 18-month sample to qualify.)

Secondary Outcomes:

- Gestational age at delivery/Preterm delivery
- Maternal morbidity
- Neonatal morbidity/mortality
- NICU admission
- Infant and Child HCV status: viral load by PCR/ HCV antibody screen

Timetable:

- Enrollment: October 2012- December 2017
- Data Collection: October 2012 – March 2019
- Closeout/Final analysis: March 2019 – October 2019