

Congenital Cytomegalovirus Infection: Randomized Placebo-Controlled Trial

Objective: To determine whether maternal administration of CMV hyperimmune globulin prior to 24⁰ weeks gestation in women diagnosed with primary CMV infection reduces the rate of congenital CMV infection.

Project Status: Currently recruiting

Clinical Centers: UAB, Ohio State, Utah, Brown, Columbia, Case Western, UT-Houston, UNC, Northwestern, UTMB-Galveston, Colorado, Duke, Stanford

Design Type: Double masked randomized clinical trial stratified by clinical center

Major Eligibility Criteria:

- Singleton gestation
- Gestational age < 24⁰ wks
- Primary CMV infection

Groups:

- Experimental: CMV hyperimmune globulin at dose of 100 mg/kg body weight
- Placebo: Matching injection (Albumin 5%/D5W)

Sample Size: 800

Scheduled Evaluations / Data Collection:

Randomization:

- Pregnancy, exposure, and medical history
- Blood (20ml) and urine (20ml) for storage

Post-Randomization:

- Every four weeks: infusion of study medication, assess side effects and open-label use
- Blood (5ml) and urine (5ml) for storage

Post-Infusion:

- Phone call to patient at 4-8 hours after the end of the first infusion (first 50 patients only)
- Phone call to patient at 16-24 hours after the end of all infusions

Delivery:

- Delivery and neonatal data

Follow-up:

- Urine and saliva on infants by 3 weeks
- Hearing by one month
- Developmental, hearing, and saliva testing of infant at years 1 and 2

Management Protocol:

Coded Medication:

- Monthly infusion (CMV hyperimmune globulin dose: 100 mg/kg or placebo) from randomization to delivery
- No open label immune globulin, ganciclovir, or valganciclovir

Outcome Measures:

Primary:

- Fetal loss or neonatal congenital CMV infection diagnosed by urine or saliva by 3 weeks of age

Secondary:

- Severity of CMV infection
- Preterm birth
- Fetal loss or death of neonatal, infant, or child
- Symptomatic CMV infection
- Sensorineural hearing loss
- Neurologic impairment
- Developmental delay

Timetable:

- Enrollment: March 2012 - March 2016
- Data Collection: March 2012 - December 2018
- Closeout/Final analysis: January 2019 - July 2019