NOVEL PRENATAL DIAGNOSTIC BIOMARKERS FOR CYTOMEGALOVIRUS INFECTION

Tech ID: 19107 / UC Case 2007-108-0

BRIEF DESCRIPTION

UCSF researchers have identified novel biomarkers of CMV replication that permit early detection of virus transmission before the onset of symptomatic disease. Quantification of these biomarkers is a more sensitive and reliable method than detection of viral DNA and therefore could result in novel tests for diagnosis of congenital infection in early gestation. Additionally, these biomarkers could be used to measure efficacy of treatment in pregnancies at high risk for congenital CMV disease and to serve as endpoints for successful antiviral therapy.

FULL DESCRIPTION

Cytomegalovirus (CMV) is the leading viral cause of congenital birth defects and lasting disabilities in the United States and affects 1% of pregnancies. Each year about 40,000 infants are born with congenital CMV infection. Of these, 8,000 will suffer permanent disabilities, including mental retardation, neuromotor abnormalities, hearing and vision loss. CMV is a common virus and about half the adult population in the United States is seropositive. Most primary maternal infections are symptomatic and diagnosed by measuring avidity of CMV-specific antibodies. Routine screening for congenital CMV infection is not currently done. For pregnancies at risk for fetal infection, ultrasound followed by amniocentesis at midgestation and PCR to detect viral DNA can identify infected fetuses with growth restriction and other abnormalities. At present, there are no diagnostic assays to detect fetal infection early in gestation or to predict symptomatic disease. Once infection is detected, therapeutic options include intravenous CMV hyperimmune globulin (HIG) and antiviral drugs. Reportedly an effective treatment, HIG reduces the likelihood of symptomatic congenital disease from 50% to 3% in infected infants. Early HIG treatment may even prevent fetal infection. Clinical trials to validate HIG and antiviral drugs show promise of producing effective therapeutics to prevent congenital CMV disease. Thus, diagnostic tests for early detection of fetal infection and prediction of treatment efficacy are desperately needed. UCSF researchers have identified novel biomarkers of CMV replication that permit early detection of virus transmission before the onset of symptomatic disease. These biomarkers, highly concentrated in body fluids, point to cellular dysfunction that precedes development of fetal disease related to birth defects. Quantification of these biomarkers is a more sensitive and reliable method than detection of viral DNA and therefore could result in novel tests for diagnosis of congenital infection in early gestation. Additionally, these biomarkers could be used to measure efficacy of treatment in pregnancies at high risk for congenital CMV disease and to serve as endpoints for successful antiviral therapy. Further studies are under way to determine the factors that contribute to pregnancy complications caused by CMV infection and to elucidate the molecular changes that enable fetal development after treatment.

FEATURES/BENEFITS

▶ Early detection of congenital CMV with increased sensitivity.
▶ Prediction of fetal disease and therapeutic efficacy.
▶ Identification of novel targets for treatment of congenital CMV infection.
**PATENT STATUS**

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**RELATED MATERIALS**

- Antibody Treatment Promotes Compensation for Human Cytomegalovirus-Induced Pathogenesis and a Hypoxia-Like Condition in Placentas with Congenital Infection
- Cytomegalovirus Impairs Cytotrophoblast-Induced Lymphangiogenesis and Vascular Remodeling in an in Vivo Human Placentation Model

**ADDRESS**

UCSF
Innovation Ventures
600 16th St, Genentech Hall, S-272,
San Francisco, CA 94158

**CONTACT**

Tel: innovation@ucsf.edu
https://innovation.ucsf.edu

Fax:

**CONNECT**

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