COVID-19 related obstetric and neonatal outcome study (CRONOS)

A novel coronavirus, termed SARS-CoV-2 (or COVID-19), has rapidly spread across the globe creating a massive public health problem. It causes potentially a life-threatening respiratory distress disease. Previous epidemics of many emerging viral infections have typically resulted in poor obstetrical outcomes including maternal morbidity and mortality, maternal-fetal transmission of the virus, and perinatal infections and death. The available literature describes only 38 pregnant women with SARS-CoV-2 with no maternal death and no evidence for intrauterine or transplacental transmission of the virus to their fetuses.

The planned study is non-interventional prospective cohort study in order to overcome the lack of knowledge about epidemiology and clinical course of SARS-CoV-2 in pregnant women to further develop evidence-based diagnostic and therapeutic recommendations. Data collection will be performed retrospectively after a pregnant patient case has been completed (treatment is finished or patient’s death). Recruitment will be bidirectional, including past patients, and prospective identification of patients with confirmed SARS-CoV-2 diagnosis. Only data from standard of care treatment will be collected (secondary data use). All data will be pseudonymised for anonymity from initial collection and entered to the online database https://castoredc.com.

At our study sites, we aim to recruit women admitted to hospital with confirmed SARS-CoV-2 in pregnancy.
This will allow for
1. the recognition of outcomes of COVID-19 infection in pregnancy for both mother and infant
2. the identification of characteristics of women who are hospitalised due to COVID-19/have a concomitant COVID-19 infection, and to determine whether these characteristics influence pregnancy and/or disease outcome

Do you plan to share individual participant data with other researchers?
Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

Protocol, ethical approval, Database will be provided for all additional study centres. Statistical analysis is “work in progress” and will be provided via URL of DGPM-online.org once established

Organizational Data

- DRKS-ID: DRKS00021208
- Date of Registration in DRKS: 2020/03/31
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
- (leading) Ethics Committee Nr.: D 451/20, Ethikkommission der Christian-Albrechts-Universität zu Kiel

Secondary IDs

- ICD10: U07.1 - Emergency use of U07.1

Health condition or Problem studied

- Arm 1: Medical history, clinical data of Covid-19 positive pregnant women will be collected during pregnancy, delivery, of the neonate and during childbed.

Interventions/Observational Groups

- Study Type: Non-interventional
- Study Type Non-Interventional: Observational study
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
Study Type: Non-interventional
Study Type Non-Interventional: Observational study
Allocation: Single arm study
Blinding: [---]*
Who is blinded: [---]*

- Control: Uncontrolled/Single arm
- Purpose: Prognosis
- Assignment: Single (group)
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

**Primary Outcome**

Trying to identify the risk/risk factors for bad outcome of Covid-19 infection during pregnancy for mother and baby until the end of the puerperium (6 weeks postpartum).

**Secondary Outcome**

Time of infection in relation to critical illness of patient, risk factors, teratogenity, embryo toxicity, course of delivery, critical ill newborn, need for intensive care of mother/child, transmission of virus to baby, bonding and breastfeeding habits

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

- University Medical Center Geburtshilfliche und pädiatrische Einrichtungen, München, Kiel, weitere

**Recruitment**

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2020/04/03
- Target Sample Size: 100
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National
**Inclusion Criteria**

- Gender: Both, male and female
- Minimum Age: no minimum age
- Maximum Age: no maximum age

**Additional Inclusion Criteria**

Proven Covid-19 infection during pregnancy and childbed

**Exclusion criteria**

deny of informed consent, withdrawal of informed consent

**Addresses**

**Primary Sponsor**

Vorstand der Deutschen Gesellschaft für Perinatale Medizin (DGPM) e.V. c/o Conventus Congressmanagement & Marketing GmbH
Mr. Privatdozent Dr. med. Ulrich Pecks
Carl-Pulvrich-Str. 1
07745 Jena
Germany

Telephone: 036413116475
Fax: 036413116240
E-mail: ulrich.pecks at uksh.de
URL: dgpm-online.org

**Contact for Scientific Queries**

Universitätsklinikum Schleswig-Holstein Campus Kiel Klinik für Gynäkologie und Geburtshilfe
Mr. Privatdozent Dr. med. Ulrich Pecks
Arnold-Heller-Str. 3
24105 Kiel
Germany

Telephone: 043150021241
Fax: [---]*
E-mail: ulrich.pecks at uksh.de
URL: uksh.de

**Contact for Public Queries**

Deutsche Gesellschaft für Perinatale Medizin c/o Conventus Congressmanagement & Marketing GmbH
Mr. Privatdozent Dr. Ulrich Pecks
Contact for Public Queries

Deutsche Gesellschaft für Perinatale Medizin e.V. Conventus Congressmanagement & Marketing GmbH
Mr. Privatdozent Dr. Ulrich Pecks
Carl-Pulvrich-Str. 1
07745 Jena
Germany

Telephone: 036413116475
Fax: [---]*
E-mail: gs at dgpm-online.org
URL: www.dgpm-online.org

Sources of Monetary or Material Support

- Private sponsorship (foundations, study societies, etc.)

im Auftrag der Deutschen Gesellschaft für Perinatale Medizin e.V. Conventus Congressmanagement & Marketing GmbH
Mr. Professor Dr. med. Rolf Schloßler
Carl-Pulfrich-Str. 1
07745 Jena
Germany

Telephone: 036413116470
Fax: 036413116243
E-mail: rolf.schloesser at kgu.de
URL: www.dgpm-online.org

Status

- Recruitment Status: Recruiting ongoing
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.