Detection of bacteria in amniotic fluid in patients with Preterm Prelabour Rupure of Membranes

Development status

Phase 2

Feasibility study. There is a realistic design of the technology and the initial tests in the laboratory are leading to the specification of the technology requirements and its capabilities.

IP protection status

Know-how

Partnering strategy

Co-development, Collaboration, investment, licensing

Institution

Fakultní nemocnice Hradec Králové

Vlastník

Fakultní nemocnice Hradec Králové

Challenge

One of the major complication of Preterm Prelabour Rupure of Membranes (PPROM) (in up to 1/3 of cases) is presence of bacteria in the amniotic fluid and / or amniotic fluid inflammation (intraamniotic inflammation). It is associated with a worse prognosis, especially for the fetus (higher morbidity, risk of death and late sequelae). To detect the bacteria in amniotic fluid of patients with PPROM is currently very time and technically demanding (including cultivation and other laboratory methods). Moreover to get the results takes days, which is too late to initiate targeted antiobiotic treatment. The solution is to dectect the bacteria in amniotic fluid using a multiplex POC (point of care) test (test performed near / at the patient's bedside) allowing the detection of multiple bacteria or their nucleic acids from amniotic fluid simultaneously, with results within hours. This will allow faster targeted treatment approach and reduce the risk of complications for both mother and fetus.

Description

Technology consists of 3 panels for multiplex RT-PCR detection of DNA of selected bacteria, that cause 88% of all intraamniotic inflammations (RT-PCR = polymerase chain reaction is a laboratory method for the enzymatic synthesis (amplification) of a defined DNA sequence). The panels contain specific sets of primers (short DNA sequences). The results of the test are interpreted by fluorescence method (specific color resolution mens presence of a specific bacteria). This method enable to determine the presence of specific bacteria in amniotic fluid in a few hours with 88% test sensitivity. Thus effective antibiotic treatment could be initiated much earlier in order to reduce the negative effects of intraamniotic inflammation on fetal damage.

Commercial opportunity

The test is intended for use in perinatological centers of intensive (12 in the Czech Republic) and intermediate (13 in the Czech Republic) care. Patients with PPROM represents about 1/3 of all preterm births and a total of 3-4% of all births. Taking into account a prevalence of approximately 110,000 births per year in the Czech Republic, it represents around 3,000-4,000 pregnant women per year suffering from PPROM. Data outside the Czech republic suggest the incidence of PPROM from 3 to 10% of all births, complicating approximately 3% of pregnancies. The technology aims to develop an in-vitro diagnostic test in accordance with EU In Vitro Diagnostic Device (IVD) Regulation 2017/746. Before entering the market IVD notification through a notified body is reguired (the dossier includes a risk management plan, performance evaluation, clinical trial, post-market monitoring). The implementation of this phase of development is expected only by the final manufacturer of the IVD test. We are currently looking for a business partner - a manufacturer of IVD diagnostics, who would be interested in the commercial use of the test.