

NEW BIOMARKERS OF SPONTANEOUS PRETERM BIRTH

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The present invention is related to the detection of a panel of specific proteins from cervicovaginal secretions, involved in extracellular matrix remodeling and immune activation, as new biomarkers to accurately predict childbirth within the following days among women with preterm labor (PTL)

PRESENTATION

Prematurity (birth before 37 weeks of amenorrhea) is the leading cause of death and perinatal morbidities / disabilities in children under five. In half of the cases, a premature birth is preceded by symptoms of preterm labor, including cervical changes and painful uterine contractions, and is the main cause of hospitalization during pregnancy (5.4% of pregnancies in France = 45,000 cases / year). However almost 75% of them will give birth at term. To date, no reliable test to assess risk of imminent delivery is available for the clinical practice, or is insufficiently precise. The new biomarkers discovered and proposed here, based on the latest advances in parturition research, emphasize specific steps of a dialogue between stromal and immune cells in the early stages of labor. They rely on secretion of proteins involved in matrix remodeling and by the activation of immunity, both being determined from a sample of vaginal secretions. Validated in two dedicated cohorts totalizing hundreds of women, these new biomarkers revealed their abilities for predicting the risk of childbirth within 24 hours, 7 days or 14 days with higher sensitivity / specificity scores compared to existing tests & markers. Current ongoing work aims to define a specific combination of those ones for set-up a first rapid, sensitive & precise test in “point-of-care” childbirth.

APPLICATIONS

- Diagnosis of imminent delivery (2h, 7 days & 14 days) in symptomatic pregnant women
- Better categorization of the risk of premature birth
- Prevent unnecessary hospitalizations, corticosteroid therapy and antibiotic therapy

DEVELOPMENT PHASE

Definition of a critical threshold and 1st determination of sensitivity and specificity in two separate series of women hospitalized for preterm labor (PTL) (105 and 127 women, respectively).

CONTACT

☎ +33 (0)1 44 23 21 50
✉ industriels@erganeo.com
Ref. project : 107

Childbirth - Prematurity - Preterm delivery
- Biomarkers - Cervicovaginal fluid

COMPETITIVE ADVANTAGES

- Better categorization of the risk of premature birth
- Optimize the care of pregnant women presenting symptoms of preterm labor
- Invention considers the dynamic and progressive mechanism of obstetric labor up to a threshold

INTELLECTUAL PROPERTY

Patent application 10.2020 (priority) EP20203980.6

PUBLICATIONS

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- Marcellin L, Schmitz T, Messaoudene M et al. Immune Modifications in Fetal Membranes Overlying the Cervix Precede Parturition in Humans. 2017. *J Immunol*. 198:1345-1356.