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Novel model of Endotracheal Catheter (FETO-balloon) for fetal endoscopic tracheal occlusion in a severe congenital diaphragmatic hernia of fetus (prospective trial)

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Abstract

Objectives: Congenital diaphragmatic hernia frequency is 1: 2000 - 1: 5000 live births worldwide. Mortality in this group in European Union and the United States is 30 - 50%. The only effective method to prevent severe CDH is fetoscopic endoscopic occlusion (FETO). But it is associated with a high risk of obstetric complications, premature birth and perinatal mortality of the fetus and newborn. Method: Thirty patients will participate in this study, divided into an intervention or control group, each containing 15 women. Entry criteria: pregnant age from 18 to 45 years, singleton pregnancy, confirmed diagnosis of severe or extremely severe left, right, or bilateral fetal CDH, normal echocardiography of the fetus, normal fetal karyotype, the mother must be healthy enough to undergo surgery, signed informed consent of patient. Exclusion criteria involve contraindications for abdominal surgery, fetoscopic surgery or general anesthesia, latex allergy, allergy or previous adverse reaction to the study drug specified in this protocol, preterm labor, pre-eclampsia or uterine abnormality, fetal aneuploidy, known structural genomic variants, other serious fetal abnormalities, or syndromic mutation, suspected primary recognized syndrome with ultrasound or MRI. We will use our developed novel model of the endotracheal balloon (FETO-balloon), which consists of a distal part (10cm) and a proximal (50cm) with a channel for the introduction of saline into the cuff of an inflatable balloon. Prevention of RDS will be immediately before the fetoscopic endotracheal occlusion or/and if there are signs of threatening preterm labor for a period of 24-34 weeks. Time for delivery: 37-38 weeks in both study groups Method of delivery: cesarean section, Method of Balloon Removal – EXIT. Results: We expect that the rates of survival and morbidity of newborns in 6 weeks, 3 and 6 months, 1 and 2 years will be higher in the intervention group. Pulmonary hypertension, the need for ECMO, the duration of mechanical ventilation, pulmonary morbidity, gastrointestinal and neurological morbidity, intrauterine infection and the length of hospitalization of the child will be assessed. Conclusions: It is expected that the use of the proposed method and the noval model of an endotracheal catheter (FETO-balloon) will avoid re-invasive fetal surgery, fetal damage and minimize the risks of postnatal complications. This assumption is going to be verified in this study. Patient recruitment is supposed to be completed by the end of 2020.

Biography

Mikhail Schneiderman-PhD in Medicine, obstetrician-gynecologist, surgeon, inventor of numerous innovative medical devices. The directions of work are infertility treatment, uterus inflammation, colpitis, adhesions, menstrual irregularities, infectious diseases, in vitro fertilization. Received Bachelor's degree from Medical University of Orenburg and Ph.D. from Medical University of Moscow. Worked as Assistant professor and gynecological surgeon. From 1979 until now Mikhail Schneiderman - the Director of the Gynecological Clinic at Old Arbat in Moscow. In 2013 Mikhail Schneiderman joined Academician V.I. Kulakov Research Center of Obstetrics, Gynecology and Perinatology Ministry of Healthcare of Russia (Moscow) as a Professor. Received various awards in the field of infertility treatment, new methods of surgical treatment of gynecological diseases, in obstetrics. More than 200 scientific publications, numerous patents in obstetrics, gynecology, urology, neurosurgery. Author of several books: "Therapeutic gynecological massage", "Gynecological massage", "Obstetric and gynecological massage".

Publications

1. New Exclusive Innovation Model of Obstetrical Pessary by Dr. Schneiderman: Preventtion and Treatment of Cervical Insufficiency and Habitual Abortion
2. Epidermolytic hyperkeratosis with polycyclic psoriasiform plaques resulting from a mutation in the keratin 1 gene.

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