BERLINER ZENTRUM FÜR
PRÄNATALDIAGNOSTIK
UND FETALCHIRURGIE

Dear colleagues!

Dear patients!

„Continuous amniotic infusion via an implanted catheter system in premature rupture of membranes (PPROM) with oligo/anhydramnios between 22+0 and 26+0 SSW“

the effect of a significant prolongation of pregnancy by continuous intrauterine amniotic infusion in patients with classic PPROM on healthy neonatal survival after one year is investigated.

The study is funded by the German Federal Ministry of Education and Research (BMBF).

The recruited patients will be randomized into two groups:

In the intervention group, recruited patients with PPROM (preterm premature rupture of membranes) between 22+0 and 26+0 weeks of gestation will receive the „Tchirikov-Amnion Flush Method“: a continuous amniotic infusion with patented artificial amniotic fluid (100 ml/h, 2.4 l/d) via a thin intrauterine catheter with an anchor system (see video) in addition to antibiotic therapy and RDS prophylaxis according to DGGG guidelines.

In the control group, patients receive only antibiotic therapy and IBS prophylaxis according to DGGG guidelines..

Primary objective

The primary objective of the study is to analyze the superiority of continuous intrauterine amniotic infusion compared with standard therapy in the treatment of premature rupture of the bladder between 20+0 to 26+0 SSW.

Inclusion criteria

- Capable pregnant women between 22+0 SSW to 26+0 SSW and status classic PPROM with oligo/anhydramnios between 20+0 to 26+0 SSW
- Pregnant women aged ≥18 years
- Singleton pregnancy
- Completed RDS prophylaxis
- Presence of written informed consent for voluntary participation in the clinical trial

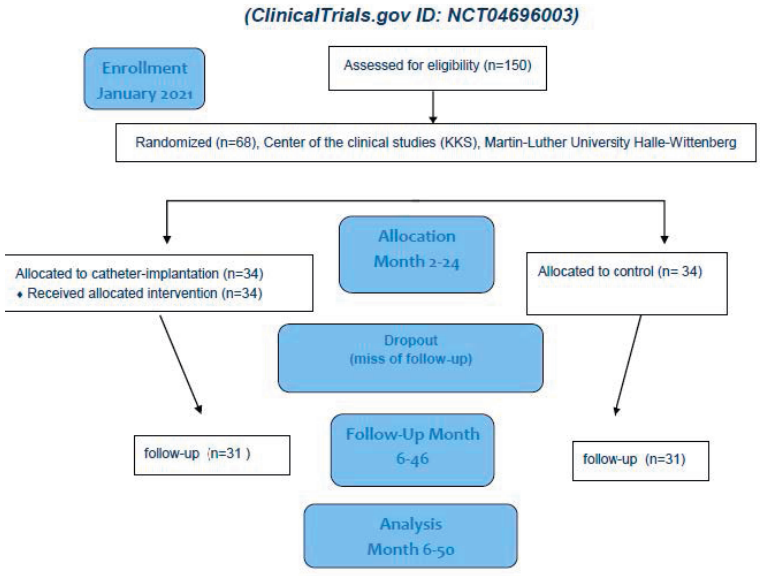
Prof. Dr. med. Michael und Dr. med. Miriam Tchirikov GbR
Nürnberger Straße 67 · 10787 Berlin
Tel.: 01525 / 755 5553
E-Mail: info@prenatal-berlin.de

Primary endpoint

The primary outcome measure is healthy neonatal survival at one year.

Healthy neonatal survival is defined as survival without any of the following complications:

- sBPD (severe bronchopulmonary dysplasia)
- intraventricular cerebral hemorrhage III-IV°
- cystic periventricular leukomalacia
- necrotizing enterocolitis (NEC) with surgical indication



If you have any further questions or if you are concerned or if you are a referring physician caring for a patient who meets the inclusion criteria for the study, please do not hesitate to contact us at 030/42206830200 or via email info@prenatal-berlin.de.

We will be happy to help you. With us you are in the best hands!

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