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| **Titel på projektet**  BEGIN STUDIET: ***B****ifidobacterium infantis* to newborns: **E**ffects of modulating the **g**ut microbial composition on infections and **in**flammatory conditions, a randomized controlled double-blinded intervention trial |
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| **Abstract**  **Background and aim:**  Growing evidence suggests that the gut microbiome plays an important role in the early development of the human immune system and the increasing number of autoimmune and inflammatory diseases, such as asthma. Modifying the gut microbiota early in life by introducing probiotics, e.g. bifidobacteria, may have beneficial effects on disease prevention. This study aims to explore effects of introducing *Bifidobacterium longum* subsp. *infantis (B. infantis)* to newborns. *B. infantis* is of special interest as a supplement to newborns, due to its superior capacity for utilization of human milk oligosaccharides, a silencing effect on Th2 and Th17 responses, and is associated with reduced abundance of antibiotic resistance genes in stool and diminished enteric inflammation. Minor clinical studies on probiotics with infant type bifidobacteria also suggest a reduction in antibiotic use and a preventative effect on eczema, while emphasizing the need for larger randomized trials.  **Material and methods:**  1000 newborn children will be included at hospitals in region Midtjylland, Denmark, in a randomized controlled intervention trial to receive B. infantis or placebo for 21 days. Outcome parameters will be measured using questionnaires, information from Danish registries and from biological samples including blood, stool and dust from the home environment. The primary clinical outcome is the incidence of bacterial infections measured as prescriptions of antibiotics. Early secondary and explorative outcomes cover infantile colic, hospital admissions, growth, asthmatic bronchitis and allergies among others.  The study initiated in June 2024 and has included approximately 200 participants so far with an overall good compliance.  **Perspectives:**  This study will evaluate potential effects of *B. infantis* administration to healthy term newborns.  Thereto it will explore associations between the early surrounding microbiome and the mother and child’s own microbiome with several health trajectories.  We aim to create a large cohort of children to be followed in many years. Additional studies will analyze later outcomes such as development of autoimmune and inflammatory diseases. |
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