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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. 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 diminished enteric inflammation and reduced abundance of antibiotic resistance genes in stool.  **Material and methods:**  1000 newborn children will be included at regional hospitals in Midtjylland, Denmark, in a randomised 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 stool samples. Primary outcome: Incidence of bacterial infections measured as prescriptions of antibiotics.  Secondary outcomes: Bowel function, infantile colic, and antibiotic resistance genes in stool.  Explorative outcomes: Asthmatic bronchitis, cow’s milk allergy, atopic dermatitis, growth, and hospital admissions.  **Perspectives:**  This study will evaluate potential effects of B. infantis to healthy term newborns. We aim to create a large cohort of children to be followed in many years. Additional studies will analyse explorative and later outcomes as development of autoimmune and inflammatory diseases |
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