KURZPROTOKOLL
PADI

Öffentlicher Titel	Prävention von allergischen Erkrankungen bei Säuglingen
Wissenschaftl. Titel	The effect of low protein, extensively hydrolyzed infant formula on allergy prevention in at-risk infants up to 1 year of age: a randomized, double-blind, controlled intervention study and the long-term effect on allergy prevention of early nutrition given in the first 120 days of life in at-risk infants until the child is 6 years of age
Kurztitel	PADI
Studienart	multizentrisch, prospektiv, randomisiert, doppelblind, dreiarmig
Studienphase	nicht zutreffend
Erkrankung	Kinder: Allergien: Nahrungsmittelallergien
Einschlusskriterien	- Age at enrollment: <= 56 days of life - Healthy term-born male and female infants (gestational Age >= 37+0, singleton birth) - Birth weight >= 2500 g and <= 4500 g - At risk of developing atopic diseases - Free of atopy symptoms at Screening and at any time before randomization - Feeding regimen at any time before Screening (V1) and Baseline (V2, infants who will receive Interventional Product (IP)): no infant formula feeding and solid foods allowed (in order to exclude prior sensitization) except amino acid formula (e.g. Neocate Infant), maltodextrin or glucose solution/gel; breastfeeding allowed - Subject's parents/caregivers willing to comply with the feeding regimen during the intervention period. Subject's parents/caregivers will decide which feeding regimen will be used (IP or breast milk): A) IP regimen (intervention or control group): only IP and breast milk until at least 120 days of life B) breastfeeding regimen (reference group): exclusively breast milk until at least 120 days of life C) No other infant formulas or solid foods are allowed - Written informed consent
Ausschlusskriterien	- Multiple births - Premature delivery (gestational age <= 36+6) - Neonatal illnesses that might have an impact on allergy development (based on Investigator's decision) - Significant congenital abnormalities - Participation in another clinical study with an IP or study method that would influence the outcome of this study - Reason to presume that the subject's parents/caregivers are unable to meet study plan requirements.
Alter	> 2 Monate
Prüfzentren	**Kinder- und Jugendmedizin** (Rekrutierung beendet) Schwerpunkt Allergologie, Pneumologie und Mukoviszidose Theodor-Stern-Kai 7 60590 Frankfurt am Main PD Dr. med. Katharina Blümchen Tel: 069 630183021 katharina.bluemchen@unimedizin-ffm.de
Sponsor	HIPP GmbH Co Vertrieb KG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03489733 (primäres Register)