

## **KURZPROTOKOLL** **PADI**

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| <b>Öffentlicher Titel</b>                        | Prävention von allergischen Erkrankungen bei Säuglingen  |
| <b>Wissenschaftl. Titel</b>                      | 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  |
| <b>Kurztitel</b>                                 | PADI   |
| <b>Studienart</b>                                | multizentrisch, prospektiv, randomisiert, doppelblind, dreiarmlig  |
| <b>Studienphase</b>                              | nicht zutreffend   |
| <b>Erkrankung</b>                                | Kinder: Allergien: Nahrungsmittelallergien   |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Age at enrollment: <math>\leq 56</math> days of life</li><li>- Healthy term-born male and female infants (gestational Age <math>\geq 37+0</math>, singleton birth)</li><li>- Birth weight <math>\geq 2500</math> g and <math>\leq 4500</math> g</li><li>- At risk of developing atopic diseases</li><li>- Free of atopy symptoms at Screening and at any time before randomization</li><li>- 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</li><li>- 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</li><li>- Written informed consent</li></ul> |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Multiple births</li><li>- Premature delivery (gestational age <math>\leq 36+6</math>)</li><li>- Neonatal illnesses that might have an impact on allergy development (based on Investigator's decision)</li><li>- Significant congenital abnormalities</li><li>- Participation in another clinical study with an IP or study method that would influence the outcome of this study</li><li>- Reason to presume that the subject's parents/caregivers are unable to meet study plan requirements.</li></ul>  |
| <b>Alter</b>                                     | $> 2$ Monate   |
| <b>Sponsor</b>                                   | HIPP GmbH Co Vertrieb KG   |
| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT03489733 (primäres Register)   |