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The Probiotics in Pregnancy Study (PiP Study): rationale and design of a double-blind randomised controlled trial to improve maternal health during pregnancy and prevent infant eczema and allergy

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Abstract

Background: Worldwide there is increasing interest in the manipulation of human gut microbiota by the use of probiotic supplements to modify or prevent a range of communicable and non-communicable diseases. Probiotic interventions administered during pregnancy and breastfeeding offer a unique opportunity to influence a range of important maternal and infant outcomes.

The aim of the Probiotics in Pregnancy Study (PiP Study) is to assess if supplementation by the probiotic *Lactobacillus rhamnosus* HN001 administered to women from early pregnancy and while breastfeeding can reduce the rates of infant eczema and atopic sensitisation at 1 year, and maternal gestational diabetes mellitus, bacterial vaginosis and Group B Streptococcal vaginal colonisation before birth, and depression and anxiety postpartum.

Methods/design: The PiP Study is a two-centre, randomised, double-blind placebo-controlled trial in Wellington and Auckland, New Zealand. Four hundred pregnant women expecting infants at high risk of allergic disease will be enrolled in the study at 14–16 weeks gestation and randomised to receive either *Lactobacillus rhamnosus* HN001 (6×10^9 colony-forming units per day (cfu/day)) or placebo until delivery and then continuing until 6 months post-partum, if breastfeeding.

Primary infant outcomes are the development and severity of eczema and atopic sensitisation in the first year of life. Secondary outcomes are diagnosis of maternal gestational diabetes mellitus, presence of bacterial vaginosis and vaginal carriage of Group B Streptococcus (at 35–37 weeks gestation). Other outcome measures include maternal weight gain, maternal postpartum depression and anxiety, infant birth weight, preterm birth, and rate of caesarean sections. A range of samples including maternal and infant faecal samples, maternal blood samples, cord blood and infant cord tissue samples, breast milk, infant skin swabs and infant buccal swabs will be collected for the investigation of the mechanisms of probiotic action.

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