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Women at risk for HPA-1a-alloimmunisation during pregnancy and subsequent FNAIT : the HPA-CARE prospective study

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Introduction: Fetal and neonatal alloimmune thrombocytopenia (FNAIT) is caused by maternal alloimmunisation against fetal platelet antigens, most commonly HPA-1a, potentially leading to thrombocytopenia and consecutive bleeding complications including intracranial hemorrhage (ICH). First pregancies are affected in approximately 50%. HLA-DRB3*01:01 positive women have a significantly increased risk for alloimmunisation. While management is established for previously affected women, management of HPA-1a–negative women without a personal or family history of FNAIT remains unclear.

Method: This is a prospective, single-centre cohort study conducted at the University Hospital Zurich. Participants are HPA-1a–negative women, aged 18–45 years, without baseline anti-HPA-1a antibodies and without history of FNAIT; partners and fetuses/neonates are assessed as mother–father–child triads. Recruitment will be primarily conducted among more than 200 pre-identified HPA-1a–negative female blood donors of the Cantonal Blood Donation Service Zurich (Blutspendedienst Zürich).

Risk stratification based on the maternal HLA-DRB3*01:01 status and the paternal HPA-1 genotype will be performed preconceptionally or in early pregnancy. The primary endpoint is defined by the rate of HPA-1a alloimmunisation in high-risk (HLA-DRB3*01:01 positive) versus low-risk (HLA-DRB3*01:01 negative) women assessed by serial antibody measurements throughout pregnancy. Secondary endpoints include maternal, obstetric, fetal and neonatal outcomes (including HPA-1 genotype, platelet counts, bleeding/ICH), the psychological burden on the parents, and healthcare resource utilization.

In case of alloimmunisation in a pregnancy with a HPA-1a positive fetus, pre-emptive intravenous immunoglobulins may be offered per current recommendations/local practice.

Result: This unique cohort will generate prospective data on: (i) alloimmunisation rates and timepoints in predefined risk categories, (ii) maternal, fetal and neonatal outcomes including thrombocytopenia and bleeding complications, (iii) psychological burden in parents, and (iv) utilisation of healthcare resources under a risk-adapted management strategy.

Conclusion: This study will address a major evidence gap in the management of previously unaffected HPA-1a–negative women by prospectively evaluating a structured, risk-adapted counseling and monitoring approach. Findings are expected to contribute to the foundation for future screening and management strategies for FNAIT in Switzerland and beyond.