Natalizumab: passage into breast milk and neonatal blood

Author(s): U. Hainke, T. Sehr, J.C. Eisele, K. Thomas, T. Ziemssen

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Undine Hainke

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Backround: Natalizumab (NTZ) is one of the disease modifying drugs for highly active relapsing remitting Multiple Sclerosis. Until now, the use of NTZ during pregnancy and lactation is off label with unknown effects on neonatal immune system. On the other side discontinuation of treatment is associated with risk of a return resp. activity rebound of disease activity.

Aim: To identify NTZ transfer into breast milk and serum of newborn babies in women who continued NTZ treatment during pregnancy and lactation.

Patients/methods: Two samples of mother milk and two pairs of serum samples from newborn babies and their mothers before NTZ infusion were analyzed for measurable free and cell bound NTZ. NTZ-treated patients served as positive control. HL60 cell based FACS assay was used for determination of free NTZ concentration, negative controls were included. For measurement of cell bound NTZ by FACS, cells were first isolated from heparinized blood and then stained with fluorescenece labeled anti-IgG4 antibody.

Results: In both newborn babies, free serum NTZ was detectable with 6,15 µg/ml and 3,06 µg/ml, while free serum NTZ concentration of 1,15 µg/ml and 5,95 µg/ml in mothers was measurable. For cell bound NTZ on CD3+ T-cells we measured MFI values of 1462 and 1855 in babies and of 830 and 1045 in mothers. In breast milk, NTZ could be only detected in one patient with 1,89 µg/ml.

Conclusion: As IgG 4-antibody, NTZ can pass placental barrier and even into breast milk. Further investigations are needed to understand these findings and to determine safety and effects on neonatal immune system of treatment during pregnancy and lactation.

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U. Hainke has nothing to disclose.

T. Sehr has nothing to disclose.

J. C. Eisele has nothing to disclose.

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