showed hypotonia. Birth head circumference was correlated with AIMS prone postural control. Follow-up head circumference was correlated to prone, supine and total AIMS scores. Smaller head circumference at birth and follow-up denoted poorer postural control.
Conclusion: Children with congenital Zika syndrome showed microcephaly at birth and follow-up. Smaller head circumferences and poorer motor outcomes were observed in 1T. Infants showed poor visual and motor outcomes. Moderate positive correlations between birth and follow-up head circumference and gross motor function were found.
Keywords: Zika Virus; Microcephaly; Child.

LB82

Effect of Ofatumumab on Serum Immunoglobulin Levels and Infection Risk in Relapsing Multiple Sclerosis Patients from the Phase 3 ASCLEPIOS I and II Trials

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Introduction: Ofatumumab, the first fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy versus teriflunomide in relapsing multiple sclerosis (RMS) patients in the ASCLEPIOS I/II trials. This study investigated serum immunoglobulin (Ig)G and IgM levels, and their associations with risk of infections in ofatumumab-treated patients.
Methods: Patients received subcutaneous ofatumumab 20 mg on Days 1, 7, and 14, Week 4, and every 4 weeks thereafter or oral teriflunomide 14 mg once-daily for up to 30 months (average follow-up: 18 months). Serum IgG/IgM levels were monitored at baseline, Weeks 4 and 12, and every 12 weeks thereafter (ofatumumab, n=946; teriflunomide, n=936). We assessed the proportion of patients with IgG/IgM levels <50% of lower limit of normal (LLN [g/L]; IgG [3.5], IgM [0.2]), and association between low IgG/IgM levels and infection rates.
Results: At Week 120, no patients reached IgG levels <50%LLN with ofatumumab (ASCLEPIOS I and II, median[g/L]: 10.57 and 9.57, respectively) or teriflunomide (10.01 and 9.65). Proportion of patients with IgM levels <50%LLN was 2.1% (n=20/944) for ofatumumab (median[g/L]: 0.91 and 0.59) and 0.6% (n=6/933) for teriflunomide (0.84 and 0.92) at Week 120. Of these, five ofatumumab-treated patients experienced infections, mostly non-serious (Grade-1/2), except one recurrent urinary tract infection (Grade-3); all infections were resolved. One patient on teriflunomide who experienced nasopharyngitis had not recovered at the time of last follow-up.

Conclusions: No reduction in serum IgG levels <50% LLN was observed with either treatment, while IgM levels decreased with both treatments; there was no apparent association with increased rate of serious/non-serious infections in RMS patients.
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LB83

Efficacy and Safety of the Bruton's Tyrosine Kinase Inhibitor (BTKI) Evobrutinib in Relapsing Multiple Sclerosis Over 108 weeks: Open-label Extension to a Phase II Study

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Introduction: In a Phase II randomised controlled trial (RCT; NCT02975349) in patients with relapsing MS, evobrutinib 75mg twice-daily (BID) reduced total T1 Gd+ lesions (primary endpoint) and annualized relapse rate (ARR) over 24 weeks versus placebo, with efficacy maintained through Week 48. We report long-term efficacy and safety from the study's open-label extension (OLE).
Methods: In the 48-week double-blind period, patients received evobrutinib 25mg once-daily (QD) or 75mg QD, 75mg BID, open-label dimethyl fumarate (240mg BID) or placebo for the first 24 weeks; all arms continued with the original treatment assignment until 48 weeks, except placebo patients who were switched to evobrutinib 25mg QD. At Week 48, all patients could enter the OLE, where treatment was initially evobrutinib 75mg QD (for approximately 48 weeks, median) before switching to 75mg BID. The OLE assessed long-term efficacy (0–108 weeks) and safety (60-week OLE) of evobrutinib.
Results: Of 267 randomised patients, 213 (80%) completed 108 weeks of treatment (48 weeks in main study and 60 weeks in OLE). For patients receiving 75mg BID in the main study, the annualised relapse rate (ARR) was 0.11 (95% CI 0.04–0.25) at Week 48, and 0.12 (0.06–0.22) for the 108-week period. Evobrutinib was generally well-tolerated, with the safety profile maintained during the 60-week OLE. Transient elevated liver aminotransferases, reported in the 48-week double-blind period, were not observed in the OLE.
Conclusions: Efficacy and safety were maintained long-term. Two Phase III RCTs evaluating efficacy and safety of evobrutinib in relapsing MS patients commence in 2020.