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Absence of Neutralizing Antibody Formation During IncobotulinumtoxinA Treatement of Spasticity in Botulinum Toxin-Naive Children With Cerebral Palsy: Pooled Analysis of Three Phase 3 Studies

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But its efficacy is lacking and even symptomatic intake to cure comorbidities or autistic symptoms itself doesn't bring long-term benefit. There should be emphasis on psycho-correctional and physical interventions including chiropractic care. Using high-velocity low-amplitude chiropractic intervention may be more beneficial in comparison to using solely psycho-correctional techniques. Although translating insights from research data into daily clinical practice is not an easy task. It takes a huge effort in terms of medical staff's education as well as clarifying the benefits of chiropractic care to patients and healthcare professionals.

Treatment: Muscle and movement

P-247 | Absence of neutralizing antibody formation during incobotulinumtoxinA treatment of spasticity in botulinum toxin-naïve children with cerebral palsy: Pooled analysis of three phase 3 studies

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Introduction: The development of neutralizing antibodies (NAbs) has been linked to secondary non-response to botulinum neurotoxin type A (BoNT-A) injections. This may be of special concern when treating conditions like pediatric spasticity. We investigated NAb formation in three large Phase 3 studies with incobotulinumtoxinA, a BoNT-A lacking complexing proteins, in children/adolescents with cerebral palsy (CP).
Patients and methods: Patients with lower-limb (LL), upper-limb (UL), or combined LL/UL spasticity (2–17 years; uni- or bilateral CP; Ashworth Scale score ≥2 in clinical patterns for treatment) received total body weight incobotulinumtoxinA ≤16–20 U/kg (max. 400–500 U) depending on the study (TIM: NCT01893411; TIMO: NCT01905683; XARA: NCT02002884) and Gross Motor Function Classification System level I–V, for up to six injection cycles (ICs). Occurrence of NAbs against BoNT-A was investigated in those ≥21 kg at screening and end of study. Blood samples were analyzed using a fluorescence immunoassay (FIA) for antibodies; positive samples were tested for NAbs using a hemidiaphragm assay.
Results: 907 patients received treatment. 386/403 (95.8%) and 318/422 (75.4%) with bodyweight ≥21 kg were tested using FIA at screening and end of study, respectively. 150/403 (37.2%) and 167/422 (39.6%) were toxin-naïve. Eleven patients tested positive for NAbs at screening and/or end of study, all of whom had previously been treated with other BoNT-As (onabotulinumtoxinA/abobotulinumtoxinA). No patient developed a secondary non-response to incobotulinumtoxinA. No toxin-naïve patients developed NAbs after incobotulinumtoxinA treatment.
Conclusions: NAb formation was not observed in toxin-naïve children/adolescents with CP treated with up to six ICs of incobotulinumtoxinA.

P-248 | Improvements in lower limb spasticity-related pain in children/adolescents with cerebral palsy after incobotulinumtoxinA injections

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Introduction: The effects of incobotulinumtoxinA on lower limb (LL) spasticity-related pain (SRP) over multiple treatment cycles (ICs) in children/adolescents (C/As) with cerebral palsy (CP) were analyzed using pooled data from three prospective phase 3 trials.
Patients and methods: C/As aged 2–17 years with CP-associated LL spasticity received incobotulinumtoxinA for 4 ICs. SRP was assessed with the Questionnaire on Pain caused by Spasticity (QPS) using C/A- (direct or via interviewer) and parent/caregiver (P/C)-completed LL modules. The pain population included all C/As with a key QPS item score >0 at baseline; post-baseline scores of 0 indicated complete pain relief.
Results: Data from 331 C/As and 841 P/Cs with data for at least one key QPS item were included. LL general SRP was reported by 178 C/As at baseline; 35.3%/49.4% of patients treated with incobotulinumtoxinA were pain-free by week 4 of IC1/IC4 ($p < 0.001$ vs baseline for all ICs), at which times C/A-reported mean LL QPS general item intensity scores had improved by 2.1/2.8 points ($p < 0.001$ vs baseline for all ICs). P/Cs observed LL general SRP in 568 C/As at baseline; 25.2%/34.1% of patients treated with incobotulinumtoxinA were pain-free by week 4 of IC1/IC4 ($p < 0.001$ vs baseline for all ICs). C/A-reported and P/C-observed improvements were generally greater with demanding tasks than at rest and more pronounced with increasing incobotulinumtoxinA ICs.