Date: 2023-01-20

Prematurely ended - statement

EudraCT number: 2015-000095-10

Full title of the study: Botulinum toxin-A as a treatment for chronic muscle-related pain in adults with spastic cerebral palsy: a randomized controlled trial.

Sponsor: Karolinska Institutet

Contact person: Kristina Tedroff, kristina.tedroff@ki.se & Dan Jacobson, dan.jacobson@ki.se

Product: BOTULINUM TOXIN A

Date of the early termination of the trial: 2018-10-05

Statement on discontinuation of the study: Study prematurely ended. The trial was stopped prematurely at the interim analysis due to a low probability of a positive primary outcome (i.e., stopped for futility) resulting in a small sample size.

Results: Fifty individuals were screened for eligibility, of whom 16 were included (10 female, 6 male, mean age = 32 years, SD = 13.3 years). The randomization yielded eight participants per treatment arm, and all completed the study as randomized. The study was stopped at the interim analysis due to a low probability, under a preset threshold, of a positive primary outcome. Four individuals were treatment responders in the BoNT-A group for the primary outcome compared to five responders in the placebo group (p = 1.000). Adverse events were mild to moderate. In exploratory analysis, the BoNT-A group had a trend of continuing reduction of pain at the last follow-up, after the primary endpoint. Conclusions: This study did not find evidence that BoNT-A was superior to placebo at the desired effect size (number needed to treat of 2.5) at 6 weeks after treatment.

Link to published article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8415259/

Registered in ClinicalTrials.gov: NCT02434549

Sofie Possmark
Coordinator
Compliance & Data Office
Research Support Office
Karolinska Institutet
Sweden