Project: The WE study (Walking Easier with cerebral palsy)

Project : Objectives	Design & Phase	Countries	Norway (coordinating)	France (Nice)	Poland (Zagórze)	No. of Patients	Investigational Medical Product (IMP)	Follow-up End points	Start Date	End Date	Outcome measures
The WE study (Walking Easier with cerebral palsy) The main objective of the present study is to investigate whether injections with BoNT-A in the calf muscles make walking easier in children with spastic CP within 6 months, reflected by reduced energy cost duringwalking. The secondaryaim is to evaluate whether there is an independent effect on activity, walking capacity, musculoskeletal pain andperceived performance and satisfaction related to mobility tasks.	**Phase IV** A double blinded placebo controlled randomized parallel-group design. Multicenter study	**Recruited Autumn 2015**	2			**96** 20 already recruited	Botox® (onabotulinumtoxin A), sterile vacuum-dried powder for reconstruction with sterile, non-preserved 0,9% Sodium Chloride injection USP. -Sterile 0,9% Sodium Chloride injection	4,12 and 24 weeks primary endpoint 12 weeks	01/01/2015	31/12/2019	**Primary:** Energy cost during walking (J/kg/m) **Secondary**: Walking capacity, walking capacity, activity, pain, percieved effect in performance and satisfaction related to mobility tasks
		Recruited Spring 2016	9								
		Recruited Autumn 2016	7								
		Recruited Spring 2017	6								
		Target Autumn 2017	**12**								
		Target Spring 2018	**11**	**5**	**6**						
		Target Autumn 2018	**10**	**7**	**9**						
		Target Spring 2019	**7**	**2**	**3**						
		Toatl : 96	**64**	**14**	**18**						

Inclusion Criteria	Exclusion Criteria
1. Diagnosed with unilateral or bilateral CP in their medical record 2. Level I or II according to Gross Motor Function Classification System. 3. Age range 4-17years 4. Signed informed consent and expected cooperation of the patients for the treatment and follow up must be obtained and documented according to ICH GCP, and national/localregulations.	1. BoNT-A injections in the lower limbs in the last 6 months 2. History of prior adverse reactions to BoNT-A (if applicable).Orthopedic surgery in the lower limbs in the last 2 years 3. No major cognitive impairments (must be able to take verbal instructions and conduct the test procedure) 4. Presence of infection at the proposed injection site(s) 5. Subclinical or clinical evidence of defective neuromuscular transmission e.g.myasthenia gravis or Lambert-Eaton Syndrome in patients with peripheral motor neuropathic diseases (e.g. amyotrophic lateral sclerosis or motor neuropathy) or other underlying neurological disorders that may be affected by BoNT-A injections 6. Pregnant or breast-feeding 7. Childbearing potential not using contraception 8. Any reason why, in the opinion of the investigator, the patient should not participate 9. Children in the need for deep sedation under treatment. Children receiving concurrent injections in the upperlimbs where deep sedation is standard procedure, are not excluded