The WE-Study; Does botulinum toxin A make Walking Easier in children with cerebral palsy?

Study protocol for a randomized double blind placebo controlled multicenter trial

Walking Easier with Cerebral Palsy

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BACKGROUND/OBJECTIVES

Despite the common use of intramuscular injections of Botulinum toxin A (BoNT-A), evidence for functional effects on walking is limited and inconclusive.

The objective is to investigate if BoNT-A makes walking easier in children with CP. We hypothesize that injections in the calf muscles will reduce energy cost during walking, improve walking capacity, increase habitual physical activity and reduce pain. The study is funded by the Norwegian health authorities and thus, independent of the pharmaceutical industry.

DESIGN (See figure)

Randomized double blind placebo controlled multicenter trial (RCT). Participants are randomized to receive either BoNT-A injections or saline water in the calf muscles. Allocation ratio is 1:1. Recruitment began in September 2015, and first results are expected in 2019.

PARTICIPANTS AND SETTING

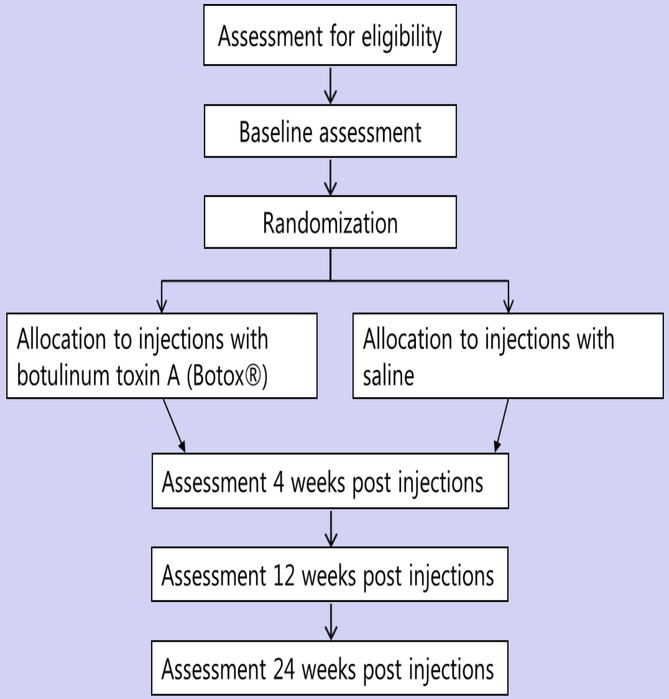
96 children; between 4 and 17 years of age.

INCLUSION CRITERIA

- Spastic unilateral or bilateral CP
- GMFCS level I or II
- Referred for single level injection of BoNT-A in the calf muscles

EXCLUSION CRITERIA

- BoNT-A in the lower limbs the past six months
- Orthopaedic surgery in the lower limbs the last two years



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MATERIALS/METHODS

Outcome measures at baseline and 4, 12 (primary endpoint) and 24 weeks after treatment.

PRIMARY OUTCOME

Energy cost (J/kg/m) during a 5 Minute Walk Test at self-selected speed.

SECONDARY OUTCOMES

1) Activity, measured with accelerometer
2) Walking capacity; distance walked (1- Minute Walk Test) and perceived exertion during walking (OMNI Rating of Perceived Exertion scale
3) Perceived change in performance and satisfaction, measured by The Canadian Occupational Performance Measure (COPM)
4) Pain

A linear mixed model will be applied to test for changes of the outcome measures between the treated and placebo groups at the defined endpoints.

ETHICS

Approved by the Regional Ethical Committee and The Norwegian Medicines Agency. ClinicalTrials.gov registration number NCT02546999.

CONCLUSIONS/SIGNIFICANCE

The study will be the largest published RCT on the functional effect of BoNT-A on children with CP that includes a homogenous population of children classified with GMFCS level I and II.

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