

**2 April, 2018**

**Dynamic Gait Index in Hemiplegic Cerebral Palsy**

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**(NCT03662139)**

**(Unique Protocol ID: 02.04.2018-113)**

## **STUDY PROTOCOL**

### **Participants**

Eligible patients with a diagnosis of Hemiplegic Cerebral Palsy, Gross Motor Function Classification System (GMFCS) level I or II, ages 6 - 14 years presented in Pediatric Rehabilitation Special Clinic in Department of Physical Medicine and Rehabilitation will be enrolled in the study. Age and gender matched typically developing (TD) children will be included in the study as a control group.

The inclusion criteria are: (1) being classified at GMFCS level I-II; (2) having a spasticity value 1, 2 or maximum 3 of the lower extremity muscles according to Modified Ashworth Scale (MAS); (3) being able to stand and walk without orthosis and any auxiliary equipment; and (4) being able to understand and execute instructions for assessment.

The exclusion criteria are: (1) having undergone botulinum toxin injection or orthopedic surgery within the last 3 months; (2) having visual impairments excluding refractive defects; (3) having any accompanying systemic disorder; (4) having uncontrolled epilepsy; (5) having the lower extremity contracture that affect the assessment; and (6) having the emergence of health problems that may affect the study.

The study will be conducted after approval from the The Institutional Human Research Ethics Committee in accordance with the Declaration of Helsinki. Informed consents will be obtained from all participating patients and their legal guardians.

### **Study design**

The study is an observational methodological research study that evaluates validity and reliability.

### **Sample size**

The sample size estimation was performed using the Gpower V. 3.1.9.3 program. According to the power analysis when  $\alpha$  error is assumed to be 0.05 (power=0.95), the minimum required sample size was calculated 28, 14 for each group.

## **Intervention**

The Modified Ashworth Scale to evaluate lower extremity spasticity and GMFCS for functional level assessment will be made to all patients.

The Dynamic Gait Index, Four Square Step Test (FSST), Timed Up and Go (TUG) and Pediatric Berg Balance Scale (PBS) will be applied for gait and balance assessment. Data collections will be conducted in a quiet room where children feel comfortable to minimize distractions. Participants will be allowed to wear daily comfortable clothes and shoes.

In the Cerebral Palsy group all tests will be assessed by two raters in the same day for interrater reliability, only DGI will be performed in two different times (approximately 7 days apart) for the test-retest reliability by the same evaluators. Two raters will not be allowed to consult each other during the test and will have no access to previous test results. In healthy control group, tests will be performed in the first session, only for once.

## **Outcome Measures**

Demographic parameters such as age, gender, height, weight, BMI, birth history such as gestational week and birth weight will be recorded initially.

### **Primary Outcome Measure**

The Dynamic Gait Index measures functionality and dynamic balance in walking and stair climbing. The DGI consists of 8 items including normal gait on flat ground, gait with speed changes, gait with horizontal head movements, gait with vertical head movements, gait and pivot turn, gait and step over obstacle, gait around obstacles and steps up and down stairs. The performance on each item is rated on a 4-point scale ranging from 0 (severe disorder) to 3 (independent walking). The total score is 24.

### **Secondary Outcome Measures**

The Four-Square Step Test evaluates the ability to change direction when performing clinical steps. It assesses dynamic balance and coordination through stepping forwards, sideways, and backwards in a timed fashion. It is a valid and reliable tool in children with cerebral palsy. The test requires the participant to step forwards, backwards and sideways over four-square shaped line in a specified sequence. The patient is asked to complete the whole sequence as soon as possible, provided that both feet touch the ground at the same time without touching the lines. Completion time is recorded for the task and longer time indicates worse ambulation and higher risk of fall.

The Timed Up and Go is a test used to measure mobility and evaluates walking speed, posture control, functional mobility and balance. Test begins with the patient sitting back in a standart chair and when asked walking 10 feet on a certain line than back to the chair sitting. Completion time is recorded for the task and longer time indicates worse ambulation and higher risk of fall.

The Pediatric Berg Balance Scale, The Berg Balance Scale (BBS) is a revised version for children by Franjoine et al. in order to assess the functions of daily life activities. The scale consists of 14 evaluations and each section is scored between 0-4; the highest score is 56. In PBS; the order of the sections in the standard BBS, is rearranged to be easy to difficult as functional sorting form, the time standards in the sections related to protection of static postures have been reduced to the pediatric population and the guidance has been simplified.