Analysis of Gait Before and After Botulinum Toxin Treatment in Patients With Focal Dystonia

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03938363	RECRUITING	MAY 6, 2019	MARCH 29, 2021

STUDY DESCRIPTION

Brief Summary

Efficient gait requires effective postural control, both static and dynamic. Hence, postural disorders may affect gait. Yet, very little is known about the specific effects of focal postural disorders such as cervical dystonia (CD) and blepharospasm (BS) on patients' mobility. The present research therefore aims at analyzing gait characteristics in patients presenting with these conditions in order to document possible gait alterations. In addition, the investigators will explore the effect of botulinum toxin treatment, which the most frequently used therapeutic option, on the patients' gait characteristics. Indeed, while the treatment improves both dystonia and pain, and therefore quality of life, its influence on gait is presently unknown. the investigators aim at filling this knowledge gap

Condition or Disease: Blepharospasm
Cervical Dystonia, Primary

Intervention/treatment: Other: Treadmill
Drug: Botulinum Toxin injection
Diagnostic Test: Severity scale of the disease

Phase: N/A

DETAILED DESCRIPTION

This is a pilot monocentric, non-randomized, controlled study. The total duration of the project is 24 months. For each patient, the total duration of the study will be one month.
The primary goal is to study gait parameters in patients with focal dystonia (CD and BS) before and after botulinum toxin treatment.
The secondary goal is to study interactions between dystonia severity and gait disorders, if gait disorders are objectified. The investigators will also examine whether botulinum toxin treatment affects gait parameters.
The main dependent variable regarding gait analysis will be gait velocity, as it is the most relevant functional variable for the patients. Gait velocity will be measured on the ground using the 10 Meter Walk Test (10MWT). Gait velocity will thereafter be adjusted to the treadmill to be the most comfortable. Spatial and temporal gait parameters will also be analyzed, namely: step frequency, step length, step length variability, gait asymmetry, and side with the shortest step length.
To examine the influence of dystonia severity on gait parameters, the investigators will examine possible links between the gait parameters and dystonia severity as reflected by the global scores of the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) for cervical dystonia and the Jankovic Rating Scale (JRS) for blepharospasm.
In order to evaluate the effects of the botulinum toxin on gait parameters, the investigators will compare gait variables before and after toxin treatment in the patient groups. If gait parameters are influenced by the treatment, the investigators will compare the post treatment data with the data of the healthy control group. In addition, the investigators will perform a patient satisfaction scale (Patient Global Impression of Change) on the change of walking parameters.
For this pilot, longitudinal, prospective, controlled study, the investigators will include two groups of 10 patients (patients with DC, patients with BS, naive or not about botulinum toxin treatment) and two groups of 10 age- and sex-matched healthy control subjects.
After collecting demographical information, severity of dystonia will be assessed using the relevant Dystonia scale (for the patients' groups).
Participants will then be shortly trained walking on a treadmill. Thereafter, they will be required to walk on a BIODEX treadmill enabling recording of all targeted gait parameters. For the patients' groups, gait parameters will be recorded both before and 4-5 weeks after the injection.
At the firth visit, the duration of assessments and treatment for the patients will be about 1.5 hour. At the second visit, assessment will last about 30 minutes.
To examine the influence of dystonia (CD, BS) on gait velocity and parameters, patients and matched healthy control data will be compared using the Mann-Whitney non parametric test. To examine the influence of botulinum toxin injection in each group of patients, data will be compared using the Wilcoxon test. Pearson correlation will be used to examine possible links between dystonia severity and gait parameters alterations.
This study will contribute to improving our knowledge on the effects of focal dystonia on gait, thus enabling an improvement in the design of rehabilitation programs. It will also document the effect of botulinum toxin on gait, thus contributing to a better guidance of this treatment.

STUDY DESIGN

Study Type:	Interventional
Estimated Enrollment :	40 participants
Intervention Model :	Parallel Assignment
Masking:	None (Open Label) ()
Primary Purpose:	Basic Science
Official Title:	Analyse de la Marche de Patients Atteints de Dystonie Focale Avant et après Traitement Par Toxine Botulique

Actual Study Start Date:	October 2019
Estimated Primary Completion Date:	June 2021
Estimated Study Completion Date:	December 2021

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Blepharospasm (BS) Patients with blepharospasm	Other: Treadmill Walk on the Biodex Gait Trainer (TM) 3 Treadmill for registration of gait parameters Gait parameters will be evaluated 5 weeks after Botulinum Toxin injection for the two experimental groups and 5 weeks after the first evaluation for the control groups Drug: Botulinum Toxin injection injection of Botulinum Toxin in the two groups of CD and BS Diagnostic Test: Severity scale of the disease JRS for BS TWSTRS for CD
Experimental: Cervical Dystonia (CD) Patients with cervical dystonia	Other: Treadmill Walk on the Biodex Gait Trainer (TM) 3 Treadmill for registration of gait parameters Gait parameters will be evaluated 5 weeks after Botulinum Toxin injection for the two experimental groups and 5 weeks after the first evaluation for the control groups Drug: Botulinum Toxin injection injection of Botulinum Toxin in the two groups of CD and BS Diagnostic Test: Severity scale of the disease JRS for BS TWSTRS for CD
Placebo Comparator: Healthy Control BS BS age- and sex-matched healthy control subjects	Other: Treadmill Walk on the Biodex Gait Trainer (TM) 3 Treadmill for registration of gait parameters Gait parameters will be evaluated 5 weeks after Botulinum Toxin injection for the two experimental groups and 5 weeks after the first evaluation for the control groups
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OUTCOME MEASURES

Primary Outcome Measures:	1. gait velocity [Time Frame: 5 minutes] comfortable gait velocity on the treadmill
Secondary Outcome Measures:	1. step length variability [Time Frame: 5 minutes] registration on the treadmill 2. step frequency [Time Frame: 5 minutes] registration on the treadmill 3. step length [Time Frame: 5 minutes] registration on the treadmill 4. step length asymmetry [Time Frame: 5 minutes] registration on the treadmill 5. shortest step side [Time Frame: 5 minutes] registration on the treadmill

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
- speaking French, in the ability to understand clinical tests and explorations,
- in ability to move to the CHU Grenoble Alpes
- Diagnosis of cervical dystonia or isolated Blepharospasm,
- Absence of neurological or psychiatric disorders,
- Affiliation to a health insurance,
- Signed consent fo the subject.
Exclusion Criteria:
- Pregnant women (positive pregnancy test), parturient or breastfeeding
- Cervical dystonia or Blepharospasm of secondary origin
- subjects having benefited from deep brain stimulation,
- History of other pathologies that may lead to walking disorders, inability to walk without technical assistance, inability to walk for more than 10 minutes,
- Subjects receiving botulinum toxin treatment for another cause.
Prohibited treatments and procedures:
- Antecedent of pathologies that may cause walking disorders
- Simultaneous participation in another Interventional study
- Subject in time of exclusion from another study
- Subject under guardianship or having curators (major protected)
- Subject under administrative or judicial supervision
- Subject not able to be contacted in case of emergency

CONTACTS AND LOCATIONS

Contacts

Locations

France, Isere	CHU Grenoble Alpes	La Tronche

Sponsors and Collaborators

University Hospital, Grenoble

Investigator

MORE INFORMATION

Other Publications

Tarsy D, Simon DK. Dystonia. N Engl J Med. 2006 Aug 24;355(8):818-29. Review.
Barr C, Barnard R, Edwards L, Lennon S, Bradnam L. Impairments of balance, stepping reactions and gait in people with cervical dystonia. Gait Posture. 2017 Jun;55:55-61. doi: 10.1016/j.gaitpost.2017.04.004. Epub 2017 Apr 4.
Albanese A, Bhatia K, Bressman SB, Delong MR, Fahn S, Fung VS, Hallett M, Jankovic J, Jinnah HA, Klein C, Lang AE, Mink JW, Teller JK. Phenomenology and classification of dystonia: a consensus update. Mov Disord. 2013 Jun 15;28(7):863-73. doi: 10.1002/mds.25475. Epub 2013 May 6. Review.

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Responsible Party :	University Hospital, Grenoble
ClinicalTrials.gov Identifier :	NCT03938363
Other Study ID Numbers :	38RC18.107, 2019-A00502-55
First Posted :	May 6, 2019
Last Update Posted :	March 29, 2021
Last Verified :	March 2021
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by University Hospital, Grenoble:	*botulinum toxin* *cervical dystonia blepharospasm* *gait parameters*
Additional relevant MeSH terms :	*Dystonic Disorders* *Dystonia* *Blepharospasm* *Torticollis*