Trial Description

Title
Use of electrical stimulation to control adductory spasmodic dysphonia (AdSD) symptoms

Trial Acronym
[---]*

URL of the trial
[---]*

Brief Summary in Lay Language
The aim of this clinical investigation is to determine whether the electrostimulation of the iSLN nerve is able to improve the adductory spasmodic dysphonia (AdSD) symptoms. The secondary objective of this clinical investigation is to further analyze the effects of the ISLN electrostimulation. Electrical stimulation seems to be a safe option for the SD treatment. The electrodes used are hooked-wire and/or needle electrodes. They will be placed without the need of anesthesia under ultrasound control. Thus, no anesthesia related risks are foreseen. After the correct placement of the electrodes, the electrodes will be connected to the external stimulator. The patients will be instructed to provide continuous oral feedback on the stimulation, in particular concerning the minimal amplitude required to feel the stimulation and the maximal amplitude they can comfortably tolerate. The amplitude and the pulse duration may be changed until a combination is found that reliably elicits swallow for 3 consecutive times.

It is the aim of this clinical investigation to evaluate for the first time the effects of electrostimulation directly delivered as close as possible to the iSLN on the control of AdSD symptoms by means of objective and subjective outcome measures.

The results obtained will help to better characterize the role of the iSLN in the development of the AdSD symptoms.

Amendment 19.NOV.2020: Arm 2 was removed in order to (1) reduce the variability and focus on the effects of the stimulation and (2) to reduce the burden for the patients (Visits for arm 2 would have required the patient to stay at the hospital for about 8h per day in comparison with the 4h required by arm 1).

Brief Summary in Scientific Language
The aim of this clinical investigation is to investigate a new therapeutic approach with objective outcome measures: the treatment of adductory spasmodic dysphonia (AdSD) symptoms.
Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: DRKS00022478
- Date of Registration in DRKS: 2020/07/23
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): no
- Ethics Approval/Approval of the Ethics Committee: Approved
  (leading) Ethics Committee Nr.: 18/19, Ethikkommission Ukraine

Secondary IDs

- ICD10: G24.8 - Other dystonia

Health condition or Problem studied

Interventions/Observational Groups

- Arm 1: After the baseline session the stimulation will be performed continuously for 30 min. After 15 min of continuous stimulation, and when the stimulation is still applied, the patient will be asked to undergo the Voice Range Profile (VRP) and to read at normal pitch:
  - 10 sentences rich in vowels
  - “The Northern Wind and the Sun”
1 hour after the stimulation the patient undergoes the following tests:
  - Voice Range Profile (VRP)
  - Maximum Phonation Time (MPT)
  - Jitter
  - Sound Pressure Level (SPL) min/max
  - F0 min/max
  - Dysphonia Severity Index (DSI)
The patient is asked to read at normal pitch:
  - 10 sentences rich in vowels
  - “The Northern Wind and the Sun”
  - Vowel analysis based on the off-line evaluation of the audiofile recording the patient sustaining each vowel for a maximum of 5s and to complete the
• overall phonation effort visual scale.

At the third and last stimulation session the patient is asked to
• undergo a videolaryngo- and -stroboscopy session and to answer the
following additional questionnaires:
• Voice Handicap Index VHI-9i
• Sydney Swallow Questionnaire
• Communicative Participation Item Bank (CPIB) - short form
• Voice Problems Questionnaire (VPQ).
• Glasgow Benefit Inventory (GBI)

The patient is asked to perform the same tests and questionnaires of the
baseline one week after the study end.

### Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: I
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

### Primary Outcome

The primary objective of this clinical investigation is to determine whether the
protocol for iSLN electrostimulation can improve the AdSD symptoms, evaluated
according to the number of spasms when the patient read 10 vowel-rich sentences
at normal pitch.

### Secondary Outcome

The secondary objective of this clinical investigation is to further analyze the
effects of the iSLN electrostimulation on the AdSD symptoms by means of the
following standardized outcome measures commonly used to evaluate voice
disorders:
• Jitter measured during the VRP assessment
• SPL range measured during the VRP assessment
• F0 range measured during the VRP assessment
• F0 measured during the reading of 10 vowel-rich sentences at normal pitch
• Voice strain analysis based on the off-line evaluation of the audiofile recording
  the patient
reading 10 vowel-rich sentences at normal pitch
• Vowel analysis based on the off-line evaluation of the audiofile recording the
  patient
sustaining each vowel for a maximum of 5s Jitter measured during the VRP
assessment
• MPT measured on [a:] during the VRP assessment
• DSI measured during the VRP assessment
• RBH
• Videolangoscopy and -stroboscopy
• VHI-9i
• Sydney Swallow Questionnaire (SSQ)
• GBI

and by means the following non-standardized outcome measures:
• Overall phonation effort estimation
• CPIB - short form
• Voice Problems Questionnaire (VPQ)

Countries of recruitment

- AT Austria
- DE Germany
- UA Ukraine

Locations of Recruitment

- University Medical Center Medizinische Universität Wien, Wien
- University Medical Center Medizinische Universität Innsbruck, Innsbruck
- University Medical Center LKH-Universitätsklinikum Graz, Graz
- University Medical Center Universitätsklinikum, Jena
- University Medical Center Universitätsmedizin Berlin, Berlin
- University Medical Center Nationalakademie der Medizinwissenschaften, Kiev

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2020/03/02
- Target Sample Size: 20
- Monocenter/Multicenter trial: Multicenter trial
- National/International: International

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age
Additional Inclusion Criteria

- Age ≥ 18 years
- Patients diagnosed with adductory Spasmodic Dysphonia, under successful botulin toxin treatment (i.e. they experienced a clinical benefit from previous botulin toxin injections within the last year), who at the time of enrolment need again a botulin toxin injection
- Signed and dated informed consent before the start of any clinical investigation-specific procedure for all the recruited subjects

Exclusion Criteria

- Lack of compliance with any inclusion criteria
- Pregnant or breast-feeding women
- Patients for whom the previous botulin toxin injection is still effective at the time of enrolment
- Patients who underwent a permanent laryngeal surgery
- Patients with chronic upper airway infections or severe respiratory diseases (e.g. COPD grade II or higher)
- Patients with diagnosed CNS diseases
- Patients suffering from any other voice disorders in addition to SD (e.g. voice tremor, supraglottic hyperactivity, other types of dystonia, etc.)
- Other clinical conditions that might result in alteration of the outcomes of this clinical investigation (e.g. ageing voice)
- Use of an active medical implant
- Known allergies or intolerance to the material used for this clinical investigation
- Parallel participation in a device/drug clinical investigation in the period of data collection, which could confound the results of the clinical investigation
- Anything that, in the opinion of the Principal Investigator, would place the subject at increased risk or preclude the subject’s full compliance with the general requirements of this clinical investigation

Addresses

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Sources of Monetary or Material Support

Commercial (pharmaceutical industry, medical engineering industry, etc.)

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Status

Recruitment Status: Recruiting ongoing
Study Closing (LPLV): [---]*

Trial Publications, Results and other documents
* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.