

Trial Description

Title

Maximum Bite Force in Patients with Spinal Muscular Atrophy during the First Year of Nusinersen Therapy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

We measure bite force in patients with spinal muscular atrophy. These patients receive a therapy with nusinersen. We hope to evaluate the effect of the therapy on the bulbar function based on the bite force measurements.

Brief Summary in Scientific Language

Spinal muscular atrophy (SMA) is characterized by progressive spinal and bulbar muscle weakness and atrophy caused by the degeneration of alpha-motoneurons. The recent approval of the antisense oligonucleotide nusinersen highlights the need for reliable clinical tools to evaluate motor function in patients with SMA. This study's aim is to test if maximum bite force measurement is suitable to quantify changes of altered bulbar function during nusinersen therapy. We want to include patients at an advanced state of SMA. In patients in an advanced stage, the maximum bite force could be a quantitative measure of the bulbar function and thus an alternative to conventional motor scales, which require residual mobility of the extremities and of the head. The aim of this study is to perform isometric bite force measurements in SMA patients to show possible changes in maximum bite force indicating changes in bulbar function. A piezoelectric force sensor registers the maximum bite force in the posterior region recorded by the CEBO-MSA64 software. Relative bite force changes in different treatment phases are analyzed.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

Only in the context of scientific publications (e.g. study protocol).

Organizational Data



- DRKS-ID: **DRKS00015842**
- Date of Registration in DRKS: **2019/07/30**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **19-1137_1 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **G12.1 - Other inherited spinal muscular atrophy**

Interventions/Observational Groups

- Arm 1: **We measure bite force in patients with spinal muscular atrophy during Nusinersen therapy (Spinraza, Biogen).**
- Arm 2: **We measure bite force in patients with spinal muscular atrophy before and during Nusinersen therapy (Spinraza, Biogen).**
- Arm 3: **We measure bite force in patients with spinal muscular atrophy without Nusinersen therapy.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Control group receives no treatment**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome



Relative changes in maximum bite force. Measured with piezoelectric transducers. Maximum bite force is repeatedly measured over the course of one year.

Secondary Outcome

Relative change of maximum bite force.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Poliklinik für Kieferorthopädie, Klinik und Poliklinik für Neurologie, Köln**
- University Medical Center **Klinik für Neurologie, Bonn**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/07/24**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **50 Years**

Additional Inclusion Criteria

Patients with spinal muscular atrophy type I or II.

Exclusion criteria

SMA type III

Addresses



■ **Primary Sponsor**

Poliklinik für Kieferorthopädie, Uniklinik Köln
Kerpener Str. 32
50931 Köln
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Contact for Scientific Queries**

Poliklinik für Kieferorthopädie, Uniklinik Köln
Ms. Dr. Teresa Kruse
Kerpener Str. 32
50931 Köln
Germany

Telephone: **0049 221 478 4712**

Fax: [---]*

E-mail: **teresa.kruse at uk-koeln.de**

URL: [---]*

■ **Contact for Public Queries**

Poliklinik für Kieferorthopädie, Uniklinik Köln
Ms. Dr. Teresa Kruse
Kerpener Str. 32
50931 Köln
Germany

Telephone: **0049 221 478 4712**

Fax: [---]*

E-mail: **teresa.kruse at uk-koeln.de**

URL: [---]*

■ **Collaborator, Other Address**

Poliklinik für Neurologie
Mr. Dr. Gilbert Wunderlich
Kerpener Str. 62
50937 Köln
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*



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Poliklinik für Neurologie
Mr. Dr. Gilbert Wunderlich
Kerpener Str. 62
50937 Köln
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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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.