

**Trial Description****Title**

**Pathophysiology of diaphragm fatigue in patients with Amyotrophic lateral sclerosis**

**Trial Acronym**

[---]\*

**URL of the trial**

[---]\*

**Brief Summary in Lay Language**

**The present study aims to investigate the pathophysiology of diaphragm fatigue in patients with Amyotrophic lateral sclerosis.**

**Amyotrophic lateral sclerosis patients will undergo a "diaphragm fatigue test" aiming at exhausting diaphragm strength under standardized conditions. Using the so called "twitch superimposition technique" both at rest and once exhaustion has been reached central and peripheral components of diaphragm fatigue can then be distinguished.**

**Central diaphragm fatigue has been hypothesized to play a role in diaphragm dysfunction in amyotrophic lateral sclerosis but not been studied in depth to date.**

**Brief Summary in Scientific Language**

**The present study aims to investigate the pathophysiology of diaphragm fatigue in patients with Amyotrophic lateral sclerosis.**

**Amyotrophic lateral sclerosis patients will undergo a "diaphragm fatigue test" aiming at exhausting diaphragm strength under standardized conditions. Using the so called "twitch superimposition technique" both at rest and once exhaustion has been reached central and peripheral components of diaphragm fatigue can then be distinguished.**

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

[---]\*

**Description IPD sharing plan**

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00016013**
- Date of Registration in DRKS: **2018/11/20**
- 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.: **2016-072-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **G12.2 - Motor neuron disease**

## Interventions/Observational Groups

- Arm 1: **10 patients with Amyotrophic lateral sclerosis will undergo placement of intraesophageal and intragastral balloon catheters in order to continuously record trans-diaphragmatic pressure after magnetic cervical phrenic nerve stimulation both at baseline (during normal breathing) and once a predefined level of diaphragm exhaustion has been reached.**
- Arm 2: **Ultimately, 10 control subjects (matched for age and gender) will undergo the study protocol described above.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
-



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Control: **Other**

Purpose: **Basic research/physiological study**

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Twitch transdiaphragmatic pressure after magnetic cervical stimulation of the phrenic nerves [cmH2O]**

### Secondary Outcome

-

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- University Medical Center **Institut für Schlafmedizin und neuromuskuläre Erkrankungen, Münster, Münster**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/28**
- Target Sample Size: **10**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria



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

#### Additional Inclusion Criteria

- a. **Age > 18 years (no age limit)**
- b. **able to consent**
- c. **likely or definite diagnosis of Amyotrophic lateral sclerosis according to the revised El-Escorial criteria**

#### Exclusion criteria

- **other severe internistic pre-existing conditions, especially insulin-dependent diabetes or severe endstage renal impairment**
- **severe neurological pre-existing conditions, especially brainstem infarction**
- **intake of opioids**
- **severe psychiatric pre-existing conditions**

#### Addresses

##### ■ Primary Sponsor

**Institut für Schlafmedizin und neuromuskuläre Erkrankungen,  
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##### ■ Contact for Scientific Queries

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URL: **https://www.ukm.de/index.php?id=6574**

##### ■ Contact for Public Queries

**Institut für Schlafmedizin und neuromuskuläre Erkrankungen**



### Contact for Public Queries

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### Sources of Monetary or Material Support

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

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Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### 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.