# Ultrasound as diagnostic tool in diaphragm dysfunction: a prospective observational study

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The primary objective of this study is to investigate the construct validity of ultrasound in diaphragm paralysis.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Neuromuscular disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON53372

**Source**
ToetsingOnline

**Brief title**
ULTRASONIC

### Condition

- Neuromuscular disorders

**Synonym**
Diaphragm dysfunction, diaphragm weakness

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken
**Source(s) of monetary or material Support:** Geen financiering

## Intervention

**Keyword:** diaphragm dysfunction, fluoroscopy, ultrasound

## Outcome measures

### Primary outcome

Concordance of diaphragm paralysis as determined by ultrasound compared with the construct for diaphragm paralysis based on traditional measurements.

### Secondary outcome

- Concordance of diaphragm paresis as determined by ultrasound compared with the construct for diaphragm paresis based on traditional measurements.

- Inter-rater reproducibility of sonographic parameters.

- Feasibility of ultrasound for diaphragm imaging

- Differences in diagnostic sensitivity and specificity of ultrasound in subpopulations with either unilateral or bilateral diaphragmatic dysfunction.

# Study description

### Background summary

The diaphragm is the main muscle for inspiration and vital for ventilation. Multiple diagnostic modalities can be performed in the work-up of suspected diaphragm dysfunction. Fluoroscopy has traditionally been the method of choice in diagnosing diaphragm paralysis and is still widely used in clinical practice, while alternative non-invasive and accessible methods have been available. Superiority of ultrasound over fluoroscopy for the diagnosis of diaphragm dysfunction has been suggested.

### Study objective

The primary objective of this study is to investigate the construct validity of ultrasound in diaphragm paralysis.

### Study design

The study will be conducted as a prospective, operator-blinded, two-center, observational study. Participants will be evaluated for diaphragm dysfunction with fluoroscopy and pulmonary function testing as in standard of care. Additionally, ultrasound will be performed.

### Study burden and risks

No risks or benefits are associated with participation of this study. Fluoroscopy is part of regular care. Study measurements include ultrasound of the diaphragm, which is non-invasive with an expected low burden for participants.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- 18 years or older
- Suspicion of diaphragm dysfunction based on medical history and/or physical examination; as determined by the treating physician.

### Exclusion criteria

- Inability for fluoroscopy (e.g. severely limited mobility, or unable to follow vocal instructions).
- Inability for diaphragm imaging (e.g. mechanical ventilation, or unable to follow vocal instructions).
- Those not able or unwilling to give written informed consent.
- Pregnant women

## Study design

### Design

**Study type:** Observational non invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 05-09-2023 |
| Enrollment: | 36 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 12-07-2023 |
| Application type: | First submission |

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL83628.075.23 |
| Other | volgt. |