

# Randomised controlled trial (RCT): Conservative voice treatment (CVT) versus electrostimulation therapy (EST) for unilateral vocal cord paresis (UVCP)

<b>Submission date</b> 13/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/10/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/12/2008	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Martin Ptok

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

CVT vs EST in UVCP: RCT

## Study objectives

Added as of 10/12/2008:

Electrical stimulation therapy is as effective as voice therapy in patients with unilateral recurrent laryngeal nerve paresis.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The study was approved by the Ethics Committee of the Hannover Medical School.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Vocal cord paresis

## Interventions

Conservative voice treatment versus electrostimulation therapy

## Intervention Type

Other

## Phase

Not Applicable

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2003

**Completion date**

31/12/2003

## **Eligibility**

**Key inclusion criteria**

Patients with unilateral vocal cord paresis

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

Added as of 10/12/2008: 90

**Key exclusion criteria**

Added as of 10/12/2008:

1. Voice therapy or any other therapy prior to T0
2. Paresis onset less than 2 weeks or more than 6 months prior to therapy
3. Age under 18 years
4. Paresis following resection of the recurrent nerve
5. Pareses due to muscle or joint injuries
6. Hearing loss 40 dB in the 500-3000 Hz range
7. Presence of other conditions possibly interfering with the therapy, such as cognitive deficits or other serious diseases

**Date of first enrolment**

01/01/2003

**Date of final enrolment**

31/12/2003

## **Locations**

## **Countries of recruitment**

Germany

## **Study participating centre**

Klinik für Phoniatrie und Pädaudiologie

Hannover

Germany

30625

## **Sponsor information**

### **Organisation**

Phoniatry and Paedaudiology Clinic, Hannover Medical School (Germany)

### **Sponsor details**

Martin Ptok

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### **Sponsor type**

Research organisation

### **Website**

<http://www.MH-Hannover.de>

### **ROR**

<https://ror.org/00f2yqf98>

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Added as of 10/12/2008:

**Funder Name**

Hannover Medical School, Clinical Department of Communication Disorders (Germany)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	final results	01/08/2008		Yes	No