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# Comparative study on treatment methods in cricopharyngeal dysfunction

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 23/07/2014 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 12/08/2014 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 29/03/2016 | Digestive System | |

## Plain English summary of protocol

Background and study aims
Cricopharyngeal dysfunction is a narrowing between the end of the pharynx (throat) and the oesophagus (food pipe) caused by the sphincter (a ring of muscle) not relaxing or a lack of coordination between the pharynx and oesophagus. Difficulty swallowing (dysphagia) is a typical symptom. In this study, we compared the effect of two different treatments: balloon dilatation and laser myotomy.

Who can participate?
Patients with swallowing problems caused by cricopharyngeal dysfunction.

What does the study involve?
Patients answered a questionnaire about their swallowing difficulties and they underwent an X-ray called videomanometry three times: before treatment, and 1 and 6 months after treatment. It took about 10 minutes. A local anaesthetic was applied in the one of the nostrils. A soft and narrow tube was introduced through the nose into the esophagus. After the cause of their swallowing difficulties was found, patients were randomly allocated to one of two treatments. The two treatment methods were opening with a balloon or laser surgery in the affected area.

What are the possible benefits and risks of participating?
The benefit for those who took part in this study is that they received consultation and treatment of their swallowing difficulties. The result of the study will help to improve the treatment of all other patients with swallowing disorders. The risk was suffering an allergic reaction to local anesthetics, although this type of allergy is very rare. The radiation dose given at the X-ray examination was not higher than it would otherwise have been exposed to as part of the routine examination of swallowing problems.

Where is the study run from?
The study ran in the Skåne University Hospital (Sweden).

When is the study starting and how long is it expected to run for?
Recruitment started in 2008. Participants have been enrolled on the study for a period of 6 months. The study ran until 2012.

Who is funding the study?
1. Skåne University Hospital (Region Skåne) (Sweden)
2. Acta Oto-laryngologica Foundation, Stockholm (Sweden)
3. Agnes Ljungren´s Found, Lund (Sweden)

Who is the main contact?
Dr Beatriz Arenaz Búa, MD
Phone: +46 40 332324; +46 762230949
E-mail: barenazb@yahoo.com

# Contact information

### Type(s)
Scientific

### Contact name
Dr Beatriz Arenaz Bua

### Contact details
ÖNH kliniken
Skanes Universitetssjukhuset
Jan Waldenström gata 18
Malmö
Sweden
205 02

# Additional identifiers

# Study information

### Scientific Title
Treatment of cricopharyngeal dysfunction: a comparative pilot study

### Study objectives
We aimed to compare treatments, at baseline and 1 and 6 months post-operative, using the Sydney Swallow Questionnaire (score should decrease when the patients feel better) and videomanometry (parameters should change i.e. sagittal diameter at UES should increase).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Lund University Ethical Committee, 22/05/2007, ref. Dnr 179/2007

### Primary study design
Interventional

### Study design
Prospective randomized pilot study

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Dysphagia, cricopharyngeal dysfunction

### Interventions
Participation meant that patients underwent an X-ray named videomanometry and answered a questionnaire about their swallowing difficulties before and 1 and 6 months after treatment. That procedure assessed the pharyngoesophageal function and anatomy. A local anaesthetic was applied in the one of the nostrils before a soft and narrow tube was introduced through the nose into the oesophagus. Treatment was decided by a process called randomisation, which is like a coin toss. Two treatment methods were available: dilation with a balloon or surgery with laser of the area between throat and oesophagus (named cricopharyngeal muscle).

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
1. Videomanometry, to assess pressure and dynamic anatomy during swallowing
2. Sydney Swallow Questionnaire, self-assessment tool, used to assign a score between 0 (no swallowing problems) and 1700 (maximum grade of swallowing problems) - completed before treatment and then 1 and 6 months after treatment

### Key secondary outcome(s)
Not provided at time of registration

### Completion date
31/12/2012

## Eligibility

### Key inclusion criteria
1. Patients with oropharyngeal dysphagia caused by cricopharyngeal dysfunction
2. Aged between 50-85 years
3. Willing to be assigned to any of the study intervention groups
4. Swallowing difficulty (dysphagia) for more than 3 months
5. Videomanometry showing cricopharyngeal dysfunction with reduction of UES diameter that exceeds 50%, high resting pressure or delayed/incomplete relaxation of UES
6. Should understand and speak Swedish

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

**Sex**
All

**Key exclusion criteria**
1. Medical instability
2. Cervical spine with osteophytes
3. Untreated gastroesophageal reflux

**Date of first enrolment**
01/01/2008

**Date of final enrolment**
31/12/2012

# Locations

**Countries of recruitment**
Sweden

**Study participating centre**
**Skanes Universitetssjukhuset**
Malmö
Sweden
205 02

# Sponsor information

**Organisation**
Skåne University Hospital (Region Skåne) (Sweden)

**ROR**
https://ror.org/02z31g829

# Funder(s)

**Funder type**
Other

**Funder Name**
Skåne University Hospital (Region Skåne) (Sweden)

**Funder Name**
Acta Oto-laryngologica Foundation, Stockholm (Sweden)

**Funder Name**
Agnes Ljungren's Found, Lund (Sweden)

# Results and Publications

## 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? |
|---|---|---|---|---|---|
| Results article | results | 10/07/2015 | | Yes | No |