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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Prospective randomized pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2008

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

Age group
Adult

Sex
Both

Target number of participants
20

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)

Sponsor details
ÖNH kliniken
Skanes Universitetssjukhuset
Jan Waldenström gata 18
Malmö
Sweden
20502

Sponsor type
Hospital/treatment centre

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

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?
Results article	results	10/07/2015		Yes	No