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Relaxation of the cervical spondylotic myelopethy histodynamic strain: Protocol for a retrospective cohort study addressing differences between anterior and posterior surgical approach.

Submission date
15/01/2016

Recruitment status
No longer recruiting

Registration date
21/01/2016

Overall study status
Completed

Last Edited
24/03/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cervical spondylotic myelopathy (CSM) is a condition caused by the wearing down (degenerative changes) of the discs and joints in the cervical spine (neck). It is the most common cause of functional problems of the spinal cord (known as myelopathy) and it is caused by compression of the spinal cord. Expansile cervical laminoplasty (ECL) and anterior cervical corpectomy and fusion (ACCF) are two surgical procedures used to treat CSM. This study looks at data from patients that have had one of these two procedures and compares them to see which leads to the most improvement.

Who can participate?
Adults with CSM that have had either ECL or ACCF surgery.

What does the study involve?
This study takes data from patients that had either ECL or ACCF between 2008 and 2013, and looks at clinical findings before surgery and then two years after surgery. This includes looking at the cervical spine using kinetic magnetic resonance imaging (kMRI), comparing how well each group of patients walked before and after their surgery and the length of their spinal cord.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Centre Zagreb (Croatia)

When is the study starting and how long is it expected to run for?
September 2008 to July 2016

Who is funding the study?
Eurospine (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Neutralization of a spondylotic cervical myelopathy dynamic compression effect: Impact of two different surgical strategies.

Study objectives
Cervical spondylotic myelopathy (CSM) backward shifting and dissociation of motion noticed following expansile cervical laminoplasty (ECL) are indicators of spinal cord relaxation. However, the two phenomena are not noticed following anterior approach surgeries. Retrospective ECL

and ACCF (anterior cervical corpectomy and fusion) cohorts will include patients with long tract symptoms and signs and tethering. Improvements of walking ability, spinal cord lengths (SCLs) and PEAs will be compared between ECL and ACCF group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Zagreb University Hospital Centre Ethics committee, 12/01/2016, ref: 02/21 AG

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cervical spondylotic myelopathy

Interventions
This study uses retrospective data from patients with cervical spondylotic myelopathy that had been treated with one of two surgical procedures - either expansile cervical laminoplasty or anterior cervical corpectomy and fusion - over a 5 year period starting from September 2008. This includes investigating preoperative clinical findings assessed according to Nurick scale, modified Japanese Orthopedic scale and Walking track analysis. Patients also underwent kinetic magnetic resonance imaging (kMRI); this was used for 3-D reconstruction for detecting tethering of the spinal cord and measurement of subaxial spinal cord length and Pia mater envelope area. All patients are then followed up for 2 years using the same clinical tests.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Walking track time, assessed as time needed to pass 30 m with one turn, preoperative, follow-up
2. Walking track steps, assessed as number of steps needed to pass 30 m with one turn preoperative, follow-up
3. Spinal cord length (SCL), assessed as the length of the central spline of the 3-D spinal cord

cylinder (SCC) rendered model
4. Pia mater envelope area (PEA), assessed as the envelope area of the 3-D SCC rendered model

Measured before surgery and at follow up.

Secondary outcome measures
1. Functional disability, measured by the mJOA grade by 2 independent investigators
2. Functional disability, measured by the Nurick scale by 2 independent investigators
3. Backward shift, comparing between preop (before surgery) and follow-up MRIs
4. Subsidence, comparison between preop and follow-up MRIs

Measured before surgery and at follow up.

Overall study start date
01/09/2008

Completion date
01/07/2016

Eligibility

Key inclusion criteria
1. Clinical inclusion criteria:
CSM classified as Nurick 3-5 in whom left sided C3-C7 open door ECL or ACCF were done for decompression
2. Radiological inclusion criteria were preoperative tethering detected by kMRI 3-D reconstructions. In addition, the patients' postdecompression spinal cords were untethered, spinal cord shifted backward and the spinal cords dissociated motion from vertebral canal. Spinal cord and brainstem transverse sections obtained from kMRI were used to render 3-D reconstructions of lower part of the brainstem and cervical and upper thoracic spinal cord. Pons to T5/T6 models were used according to the following criteria:
3. Spinal cord tethering: At the point of maximum compression canal compromise is graded 3 (pincer effect); through extension to flexion neck movement the two separate segments of the spinal cord changes the length. Pincer effect divides this two segment.
4. Spinal cord untethering and dissociation of motion: The spinal cord and subarchnoidal space are without compression and therefore graded as 0. The spinal cord homogeneously increases its length from extension to flexion. Preoperative spinal cord 3-D model represents original spinal canal and is compared with postoperative. Dissociation of motion is considered when postoperative 3-D model does not cover pre-opartative, but is shorter and less curly.
5. Backward shift: Preoperative subaxial spinal cord central spline was superposed on the central spline created on the postoperative images. Backward shift is considered when instead of superposing of two lines the postoperative central spline is placed porsterior to the preoperative

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
60

Key exclusion criteria
Patients with:
1. Kyphosis more than 10 degrees
2. Instability
3. Metabolic or inflammatory bone disease
4. Tumor
5. Multiple sclerosis
6. Anterolateral sclerosis
7. Toxic-metabolic myelopathies

Date of first enrolment
01/09/2008

Date of final enrolment
31/08/2013

Locations

Countries of recruitment
Croatia

Study participating centre
University Hospital Centre Zagreb
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/00r9vb833

Funder(s)

Funder type
Government

Funder Name
Eurospine (Switzerland)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/09/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date