



POsterior Laminectomy and FIXation for Degenerative Cervical Myelopathy [POLYFIX-DCM]

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Degenerative cervical myelopathy (DCM) is the most common cause of spinal cord dysfunction in adults and is associated with a significantly reduced quality of life. Patients commonly present with progressive neurological deficits, such as numb and clumsy hands, imbalance, frequent falls, loss of mobility and urinary incontinence, complemented by magnetic resonance imaging changes. Whilst DCM symptoms can remain mild and stable, disability may progress and if left unchecked or undiagnosed, may progress to complete paralysis.

Surgery to decompress the spinal cord is the only evidence-based treatment for DCM. Surgery may be performed via either an anterior or posterior approach to the spine. Particularly in the UK, the two main posterior options are laminectomy alone and laminectomy and fusion. For cases of multi-level DCM, optimal treatment remains unknown. Currently, the choice of surgical procedure (laminectomy alone vs. laminectomy and instrumented fusion) is left to the discretion of the treating surgeon, leading to variation in practice. Consequently, establishing the optimal surgical management for cases of multi-level DCM treated posteriorly remains an unmet clinical need, with implications for both the patients and healthcare providers.

POLYFIX DCM will therefore address the following hypothesis:

Laminectomy and fusion improves outcomes following surgery for multi-level degenerative cervical myelopathy when compared to laminectomy alone.

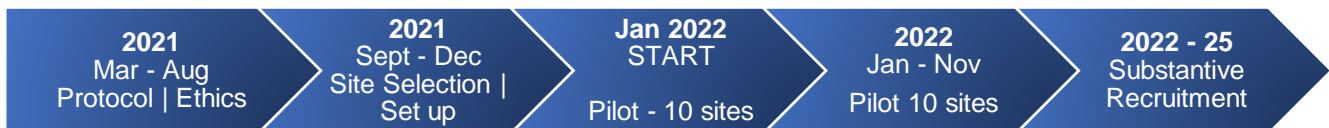
POLYFIX DCM will be a multi-centre pragmatic, randomised trial, with blinded outcome assessment, aiming to determine the comparative clinical- and cost-effectiveness of decompression and fusion, with decompression alone for multi-level DCM treated posteriorly. The primary objective of POLYFIX DCM is to detect a mean difference of 1 point in the mJOA scale at 24 months post-surgery between the laminectomy alone group and the laminectomy and fusion group. Pain, quality of life, surgical complications, cost-effectiveness



and radiological measures will also be assessed between the two groups. Total follow up will be for 24-months, with assessments at 6, 12 and 24-months post-surgery.

POLYFIX DCM aims to recruit 394 patients in total. To be eligible, participants must be aged >18 years, have an established diagnosis of DCM (clinical and radiological findings) and be scheduled for posterior surgery involving 2 or more consecutive cervical laminae. Patients with mild and non-progressive DCM (mJOA score >16 at two consecutive time points) or presenting in the context of acute trauma will be ineligible.

Project timeline:



For further information on the trial, or to express interest in participating, please contact Mr Benjamin Davies bd375@cam.ac.uk or follow the QR link below.

