

SUcceSS trial

Central lumbar spinal stenosis (LSS) is a common cause of pain, reduced function and quality of life in older adults. Current management of LSS includes surgery to decompress the spinal canal and alleviate symptoms. However, evidence supporting surgical decompression derives from unblinded randomised trials with high cross-over rates or cohort studies showing modest benefits. This protocol describes the design of the SURgery for Spinal Stenosis (SUcceSS) trial -the first randomised placebo-controlled trial of decompressive surgery for symptomatic LSS. METHODS AND ANALYSIS:

SUcceSS will be a prospectively registered, randomised placebo-controlled trial of decompressive spinal surgery. 160 eligible participants (80 participants/group) with symptomatic LSS will be randomised to either surgical spinal decompression or placebo surgical intervention. The placebo surgical intervention is identical to surgical decompression in all other ways with the exception of the removal of any bone or ligament. All participants and assessors will be blinded to treatment allocation. Outcomes will be assessed at baseline and at 3, 6, 12 and 24 months. The coprimary outcomes will be function measured with the Oswestry Disability Index and the proportion of participants who have meaningfully improved their walking capacity at 3 months postrandomisation. Secondary outcomes include back pain intensity, lower limb pain intensity, disability, quality of life, anxiety and depression, neurogenic claudication score, perceived recovery, treatment satisfaction, adverse events, reoperation rate and rehospitalisation rate. Those who decline to be randomised will be invited to participate in a parallel observational cohort. Data analysis will be blinded and by intention to treat. A trial-based cost-effectiveness analysis will determine the potential incremental cost per quality-adjusted life year gained. ETHICS AND DISSEMINATION:

Ethics approval has been granted by the NSW Health (reference:17/247/POWH/601) and the Monash University (reference: 12371) Human Research Ethics Committees. Dissemination of results will be via journal articles and presentations at national and international conferences. TRIAL REGISTRATION NUMBER:

ACTRN12617000884303; Pre-results ¹⁾.

¹⁾

Anderson DB, Ferreira ML, Harris IA, Davis GA, Stanford R, Beard D, Li Q, Jan S, Mobbs RJ, Maher CG, Yong R, Zammit T, Latimer J, Buchbinder R. SUcceSS, SURgery for Spinal Stenosis: protocol of a randomised, placebo-controlled trial. *BMJ Open*. 2019 Feb 13;9(2):e024944. doi: 10.1136/bmjopen-2018-024944. PubMed PMID: 30765407.

From:

<https://neurosurgerywiki.com/wiki/> - **Neurosurgery Wiki**

Permanent link:

https://neurosurgerywiki.com/wiki/doku.php?id=succes_trial

Last update: **2024/06/07 02:54**

