

NEWSLETTER

POsterior Laminectomy with FIXation for MultiLevel Degenerative Cervical Myelopathy

POLYFIX DCM

NEWSLETTER ISSUE 3, Oct 2022

Welcome to the third edition of the **POLYFIX DCM** newsletter

Welcome, Royal Victoria Infirmary (Newcastle) & Queen's Medical Centre (Nottingham) !

In the past month, we have opened Royal Victoria Infirmary (Newcastle) and Queen's Medical Centre (Nottingham), and two other sites will be opened soon: St. Mary's Hospital (Imperial College) and St George University Hospital. Ten patients in total have now been randomised into the POLYFIX DCM trial! In December, the NIHR will review our performance (the 'internal pilot') focused on our ability to deliver on this trial. To show this we do not only need to show that sites are opening, but more importantly that there is recruitment within the opened sites. A recruitment of 1-2 patients per site before the end of this year is vital in order to pass the internal pilot phase, thus we will look forward to receiving more good news with more randomised patients from the already opened sites, and keep welcoming new sites to our effort!

Mark Kotter and Ben Davies

POLYFIX in numbers

SITES OPEN

7

Addenbrooke's Hospital (Cambridge)
Royal Derby Hospital
King's College Hospital
Royal Infirmary of Edinburgh
Royal Orthopaedic Hospital (Birmingham)
Royal Victoria Infirmary (Newcastle)
Queen's Medical Centre (Nottingham)

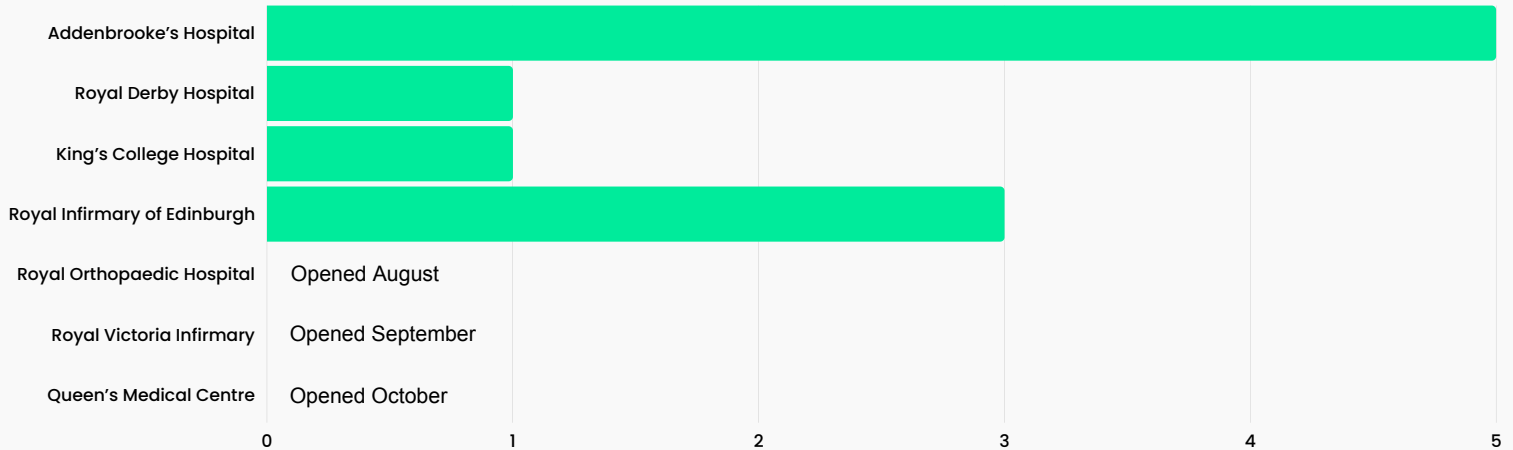
PATIENTS RECRUITED

10

Addenbrooke's Hospital Cambridge (5)
Royal Infirmary of Edinburgh (3)
Royal Derby Hospital (1)
King's College Hospital (1)

SITES IN SET UP

20



The Big Ask: What can you do this month for POLYFIX?

CC: xiaoyu.yang@addenbrooks.nhs.uk

Dear Investigator,

Where are we up to with POLYFIX-DCM? The trial is now up and running, and recruiting elsewhere. Email your R&D team for an update of your local setup.

I have copied the trial's manager in Xiaoyu as well, in case there is anything you need from us do not hesitate to contact us.

POLYFIX DCM

Contact Info
CI: Mark Kotter
Co CI: Ben Davies
Clinical fellow: Stefan Yordanov
Trial coordinator: Xiaoyu Yang
Official Website: <https://polyfix-dcm.com>

Current documents version & Update info

Protocol: version 2.0 (please only use it after local R&D has issued the C&C confirmation)
Paper based CRFs: version 2.0 ((please only use it after local R&D has issued the C&C confirmation)
E-CRFs: Being tested
Trial Manual: version 1.4
SAE form: version 1.0

Others

1. The Protocol version 2.0 has been approved by REC & HRA, and it is being reviewed in your R&D. Once in receipt of the C&C confirmation, the new protocol and CRFs can be used. The main changes to be aware of are (1) A procedure to enable virtual (over the telephone) consent, to support virtual clinics and (2) Clearer documentation, including the breakdown of CRFs into packs, to ensure the it is apparent which assessments should be done, and who should organise them, at each time point

2. The Myelopathy.org Award for Outstanding Research 2023, is open for submissions. Deadline is 1st November. It is open to any completed study, either published in 2021/22, or unpublished and in manuscript form, that aligns with the top research priorities for DCM. Submissions should be emailed to liz@myelopathy.org.