The Pre-BRA Study Newsletter Winter 2020

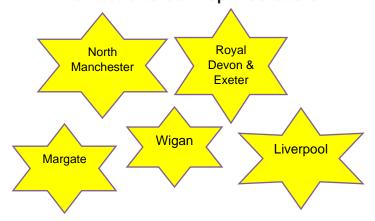
prebra-study@bristol.ac.uk



Pre-BRA Study is recruiting well!

With end of recruitment June 2020 in sight, we are actively recruiting and are now more than halfway through! And we are excited! Currently, we are open at 42 sites, 10 of which have been recruited in the last two months. And we have over 167 patients in the study! Not all open sites are recruiting yet. If you have not started with recruitment, we encourage you to get in touch. The first patient was recruited on June 26th 2019 in North Manchester. Overall, we have 48% of our total recruitment target! With so many more sites coming on board, we are confident we will reach our target in June 2020. Thank you all!

Well done to our Top Recruiters



Thank you for all your efforts.

We do not have a recruitment cap, so PLEASE keep recruiting until the end of June 2020.

Data Collection: The primary outcome implant loss at 3 months, is now due for some patients.

Thank you very much for completing this in a timely manner. This data point is essential for our data analysis. We will be doing the initial data analysis after we have collected 125 primary outcomes.

3 months data collection: Please complete the CRFs at 3 months. We are allowing an extra month for the 3 months data collection timepoint. This should be collected by 4 months at the latest please. Please can you record the consent and eligibility questions (before the operative data section). These are central teams' records of consent.

REDCap Notes: Please do enter withdrawals and create a CRF for the paper opted questionnaires. The following fields are important for REDCap in order to get the PROMs emailed to patients. Please make sure you answer these questions when you first create the CRFs:

- Questionnaire completion question
- Patient emails
- Actual date of surgery (in section 4, operative data) – NOT planned date of surgery

Please rest assured we are uploading recruitment onto the CPMS system.

Are you a trainee recruiter for Pre-BRA?

The study is part of an NIHR/ RCSE badged **Associate Principal Investigator** (API) scheme. Please get in touch with the study team if you would like to be recognised as API at your site. More information on the scheme is available on the NIHR website:

https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/11694?diaryentryid=53625

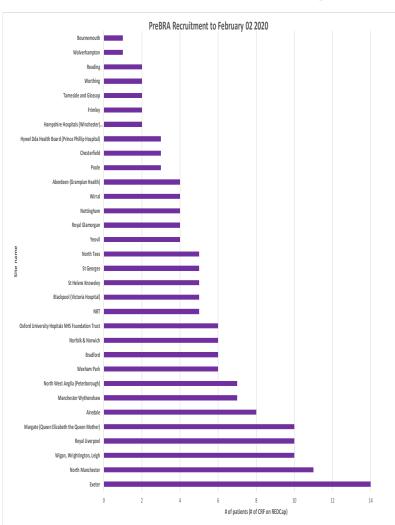
https://www.nihr.ac.uk/explorenihr/specialties/surgery.htm

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CONGRATULATIONS to all our recruiting centers!



Well done to all of you!

Thanks for all your hard work so far! Please note: The study team will use the date that you create a REDCap™ record for each patient as their date of recruitment for CPMS records.

Surgeon Interviews

Have you modified your patient selection criteria or intraoperative technique for prepectoral reconstruction?

If so, please report the modification via REDCap™ patient Case Report Forms (CRFs).

Have your patients experienced any complications within 3 months?

Our primary outcome is implant loss at 3 months following surgery. Please respond to this on the CRF and describe if there have been complications.

The short telephone interviews (10-15 mins) will start soon. We look forward to reporting the results and "sharing learning" amongst surgeons soon.

Baby News

You all will be delighted to know that Kate has had a smooth delivery. Sophie Evelyn Irene Bayliss was born 15th Nov at 2.30am weighing 8lbs. Mum and baby are both doing well, and big sister Ellie is delighted. Thank you all for supporting Parisa through her new role. If you need to contact the Pre-BRA team, you can email Parisa on the dedicated study email: prebra-study@bristol.ac.uk

Network: www.ibranet.co.uk and

@weare_iBRANET

Please contact prebra-study@bristol.ac.uk PreBRA mobile: 07815684182