Title	**MAP-BRA 1 – FORTIVA** A **M**esh s**A**fety Platform for immediate implant based **BR**e**A**st Reconstruction. A multicentre prospective cohort study to evaluate the safety and effectiveness of Fortiva porcine acellular dermal matrix in immediate implant based breast reconstruction
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Patient population	Inclusion criteria: • Female patients age 18 or over electing to undergo immediate implant based reconstruction with mesh for invasive or pre-invasive cancer or for risk reduction. Exclusion criteria: Patients undergoing: • Revisional surgery • Delayed breast reconstruction • Previous breast or mantle radiotherapy • Patients who are allergic to pork or unwilling to have a porcine product • Patients unable or unwilling to give informed consent • Patients unable to complete patient reported outcome questionnaires • Patients considered by their surgeon to be unsuitable for mesh reconstruction • Patients who currently smoke cigarettes or e-cigarettes • Patients with a BMI of 35 or above • Patients in whom it is anticipated that an implant volume of greater than 500cc will be required.
Background and rationale	Mesh assisted implant based reconstruction has been widely adopted into UK practice despite limited evidence to support its safety and efficacy. Some concerns have been raised regarding excessive early complication rates with mesh products. High quality prospective outcome data is needed to inform patients and surgeons about the safety and efficacy of these products. The iBRA study has collected data on over 2000 UK patients undergoing immediate implant based breast reconstruction. It demonstrated that a variety of

	devices both biological and synthetic were in use and highlighted that surgical practice has continued to evolve with mesh now used for complete implant coverage – prepectoral reconstruction. The study provides a bench mark for evaluating outcomes of implant based reconstruction demonstrating an implant loss rate of 9% at 3 months. Fortiva is a novel porcine acellular dermal matrix produced by RTI Surgical. It is perforated unlike standard ADMs . As a larger sheet it is marketed for both prepectoral implant reconstruction (PPIR) and sub pectoral breast reconstruction (SPIR) and may offer patients and surgeons a more effective and cost-effective alternative to other xenogenic ADMs (e.g. Strattice, SurgiMend, Braxon) in the UK and human products (e.g AlloDerm) in North America. Robust evaluation, however, is necessary to demonstrate safety and effectiveness of the product before it is introduced into routine practice. We propose an IDEAL 2a/b prospective observational study. Phases 2a and 2b establish the risks and benefits of a technique, ensuring stability of the procedure and evaluating the learning curve before proceeding to formal evaluation. We plan to evaluate the safety of Fortiva mesh in both SPIBR and PPIBR using data from the iBRA study cohort for comparison. Safety will be measured by implant loss and complication rate at 3 months and 18 months post operatively. Patients undergoing both SPIBR and PPIBR will be recruited to the study. After recruitment of 46 patients there will be an interim analysis to confirm the safety of the product. If the rate of implant loss is considered acceptable (less than 5 implant losses) the trial will continue to recruit a total of 79 patients. The interim analysis will also allow a pause for group learning and transparent reporting of technique modifications. Root cause analysis will be conducted for every implant loss prior to proceeding to the next phase.
No of patients	79 patients
No of centres	10 centres Recruiting units will have experience of Mesh based reconstruction and be able to demonstrate a 3 month implant loss rate of <10%
Primary objective	The aim of this study is to robustly evaluate the safety and effectiveness of Fortiva in implant based breast reconstruction by comparing standardized clinical and patient-reported outcomes with data from the NIHR funded iBRA study.
Primary end point	Implant loss rate at 3 months following immediate implant based breast reconstruction with Fortiva
Secondary end points	• Complications of immediate implant based reconstruction with Fortiva at 3 months • Complications of immediate implant based reconstruction with Fortiva at 18 months • Implant loss rate at 18 months following immediate implant based reconstruction with Fortiva
Secondary objectives	To evaluate product handling and surgeons' experience of using Fortiva in subpectoral and prepectoral implant reconstruction using a self-report questionnaire. To establish a platform for the evaluation of new Mesh products in breast reconstruction
Trial duration	36 months

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Key references	Potter S, Browning D, Savović J, Holcombe C, Blazeby JM. Systematic review and critical appraisal of the impact of acellular dermal matrix use on the outcomes of implant-based breast reconstruction. British Journal of Surgery 2015;102(9): 1010-1025. Hallberg H, Rafnsdottir S, Selvaggi G, Strandell A, Samuelsson O, Stadig I, Svanbeg T, Hansson E, Lewin R. Benefits and risks with acellular dermal matrix and mesh support in immediate breast reconstruction: a systematic review and meta-analysis. J Plast Surg Hand Surg 2018;52(3): 130-147. Potter S, Conroy E, Williamson P, Thrush S, Whisker LJ, Skillman JM, Barnes NLP, Cutress RI, Teasdale EM, Mills N, Mylvaganam S, Branford O, McEvoy K, Jain A, Gardiner M, Blazeby JM, Holcombe C. The iBRA (implant Breast Reconstruction evAluation) Study: Protocol for a prospective multicentre cohort study to inform the feasibility, design and conduct of a pragmatic randomised clinical trial comparing new techniques of implant-based breast reconstruction. Pilot and Feasibility Stud 2016;2:41 ecollection2016. McCulloch P, Altman DG, Campbell WB. No surgical innovation without evaluation: the IDEAL recommendations. Lancet 2009; 374:1105-112.