



Single Use Negative pResure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation Introduction

UNIVERSITY OF BIRMINGHAM |  Birmingham Clinical Trials Unit |  |  NORTH WEST RESEARCH COLLABORATIVE | 

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Introduction



- **Funders:** NIHR RfPB
- **Sponsor:** University of Birmingham
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Role of BCTU



- ❑ Site set-up
- ❑ Trial coordination according to:
 - Good Clinical Practice
 - UK Policy Framework for Health and Social Care Research
 - UoB and BCTU SOPs
- ❑ Protocol guidance
- ❑ Queries (e.g. patient pathway, eligibility)
- ❑ Randomisation via CHaRT (University of Aberdeen)
- ❑ Data collection, entry and management
- ❑ Receipt and review of SAEs
- ❑ Monitoring
- ❑ Statistical analysis (health economics analysis undertaken by NWSTC)
- ❑ Database creation and maintenance
- ❑ Coordination of trial supplies; communicate with Smith & Nephew to initiate supply and request resupply



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Site-specific Training objectives



<p><u>PART 1</u></p> <ul style="list-style-type: none">❑ Trial overview (background, rationale, trial design)❑ Primary & secondary objectives & outcomes❑ Patient eligibility (inclusion & exclusion criteria)❑ Trial schema	<p><u>PART 4</u></p> <ul style="list-style-type: none">❑ Safety reporting
<p><u>PART 2</u></p> <ul style="list-style-type: none">❑ Participant identification and consent❑ Randomisation procedures❑ Intervention	<p><u>PART 5</u></p> <ul style="list-style-type: none">❑ Delegation of duties and training❑ Authorship policy and Associate PI scheme❑ PI oversight❑ Compliance, monitoring and audits❑ Confidentiality❑ Investigator site file❑ Archiving
<p><u>PART 3</u></p> <ul style="list-style-type: none">❑ Trial activities, paperwork and CRFs including patient discontinuation❑ Assessment schedule❑ Source data	<p><u>PART 6</u></p> <ul style="list-style-type: none">❑ SUNPD supplies❑ Other trial supplies



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Thank you

Please contact us if you have any questions...

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