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ROSSINI-Platform - a 'Basket Factorial Multi Arm Multi-Stage (MAMS)' Platform Trial in Surgical Site Infection: The Breast Pillar

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BACKGROUND

- Breast cancer is the most common cancer in the UK, accounting for 15% of ***all*** new cancer cases, with almost 57,000 new cases every year.
- Around **90% of breast cancers will be treated with surgery**, and 76% of people diagnosed with breast cancer will survive 10 years or more.
- As most breast cancer patients survive for a long-time following treatment, patient experience as well as a variety of outcomes including cosmesis, quality of life and oncological outcomes such as recurrence, are very important.
- **Surgical Site Infection (SSI)**
  - SSI most common healthcare complication
  - 250K NHS patients/year
  - **£700million treatment costs/yea**
  - Patient pain & suffering
- **SSI after breast surgery can profoundly impact both patient experience and outcomes** including cosmesis, a delay to adjuvant treatment and potentially increase the risk of breast cancer recurrence.
- **Few interventions to reduce SSI are underpinned by high quality evidence**, and consequently there is wide variation in practice to reduce SSI across the UK and the world.

OUTCOMES

SSI within 30 days of surgery

- Evaluated through a centralised remote wound assessment hub after discharge using wound 'selfies'

Secondary outcomes

- Quality of Life
- Health Economics

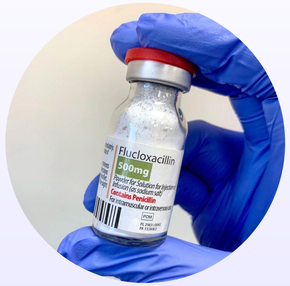
Added value

- Methodological knowledge - efficient RCT design
- Global fight against antimicrobial resistance
- Carbon impact modelling
- Collaboration across institutions and specialties

METHODS

Full-scale RCTs will be delivered in parallel in six surgical specialties (breast surgery, vascular limb and groin, obstetrics, neurosurgery and cardiothoracic surgery), utilizing active learning and cross-cohort transfer of interventions (and/or combinations of), that suggest evidence of benefit.

Selected initial INTERVENTIONS/COMPARATORS in breast surgery



1. Prophylactic antibiotics prior to surgery Vs None



2. Wound irrigation with warm Granudacyn® prior to closure Vs Standard of care



3. Dialkylcarbomoyl chloride (DACC)-coated dressings Vs Standard of care

INTERVENTIONS IN OTHER SPECIALTIES *(for potential cross-cohort transfer)*

Negative pressure wound therapy | Glove & instrument change | Hair waxing/epilation | Topical vancomycin | Gentamycin sponge | Double vs single skin preparation | Continuous vs interrupted skin closure | Large volume wound irrigation

CONCLUSION

ROSSINI-PLATFORM is methodologically unique

- **Highly efficient** trial design
- Will provide **practice changing results improving patient outcomes in a more time and cost-effective manner than traditional trials**
- Recruitment starts **JANUARY 2026**
- **3-month initial pilot** with stop/go progression criteria
- **5-year project** with recruitment over 50 months

POPULATION

- Adults >/= 18yrs
- Undergoing resectional surgery for breast cancer including:
  - Breast conservation surgery
  - Mastectomy
  - Oncoplastic surgery
  - And/or axillary surgery.

Exclusion

- Patients undergoing whole breast reconstruction (implant and autologous)
- Re-excision of margins

	Breast Surgery
Baseline SSI Rate	5%
Intervention arm SSI rate	3%
Absolute Risk Reduction	2%
Overall sample size needed	4280
Annual operation pool across whole UK	45,000 operations/yr
Potentially eligible population	80% = 36,000/yr
Proportion of UK breast units open for trial	50% = 18000/yr
Tangibly recruitable population	30% = 5940/yr
Total patients available over 50-month recruitment	24,750

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