EMERGING TRIALS

INTRODUCTION

This cheat sheet compiles trials that are in progress or are completed but yet to report.

SCREENING AND IMAGING TRIALS

BRAIDS trial

- Multicentre RCT with 4 arms
    - Standard of care
    - Automated breast ultrasound (ABUS)
    - Contrast-enhanced spectral mammography (CESM)
    - Abbreviated breast MRI (AB-MRI)
- Supplemental imaging is preformed at baseline and repeated 18 months later. All participants are followed-up for up to two subsequent screening rounds. The primary outcome measure for the trial is the cancer detection rate in each arm.

MIPA trial

- Run by the same centre (Prof. Fiona Gilbert) as BRAIDS trial.
- Looks at whether MRI pre-operatively increases mastectomy rate. The Dutch guidelines summarise this.

BREAST RADIOTHERAPY

PRECISION (planned completion 2025)

- Phase II study to explore if patients aged 50-70 years can avoid radiotherapy post WLE.
- PAM 50 used to prognosticate and create a low-risk arm which will then have the option to omit radiotherapy and an arm of intermediate/high risk who will receive radiotherapy.
- T1, ER+ (≥10%) or PR+, HER2- and grade 1 or 2. LN status - all included.
- 5yr LRR is primary and then Any recurrence/OS/DFS secondary.
- NB LORD, COMET will be combined to produce predictive tool

PRIMETIME (UK, Closed to recruitment 31/03/2022. Currently in follow-up)

- Can patients aged 60+ years, low risk avoid radiotherapy post WLE
    - T1 N0 M0, G1-2, ER+, HER2-
    - Additional build in, Ki67 testing
    - Willing to take 5yrs adjuvant endocrine therapy

Emerging trials.
Originally collated by Miss Amy Robinson. Last updated: February 2025

De-Escalation DCIS

LORIS (planned completion 2020, not yet reported)

- Phase III trial surgery versus surveillance for low-risk DCIS

COMET/LORD/LORETTA

- Similar trials running in the USA, Netherlands and Japan respectively.
- Combined in **ALLIANCE** with biomarkers - precision.

Radiotherapy after Mastectomy

SUPREMO (Selective Use of Post-operative Radiotherapy aftEr MastectOmy, closed in 2020. 2 year QUAL reported currently)

- RCT multi-centre international trial
- Intermediate risk – do they benefit from radiotherapy?
- Post-mastectomy/ANC
- includes T3N0; T2N0 with high-risk features; T2N1.
- Excludes T3N1; T4 and N2+
- Post NAC the criteria are the same – taken as what they were pre or what they are post e.g. ANC post NAC 1-3 nodes eligible but 4+ nodes excluded. T4 prior not included regardless of response.

De-Escalation Breast Surgical

SMALL

- Phase III trial surgery versus surveillance for low risk to get VAE
  - Non-inferiority multi-centre RCT in the UK
  - VAE: Surgery 2:1 randomisation of G1, <15mm, age >47, ER/PR+ and HER2-
  - NB: those with successful VAE full excision (assessed on repeat mammogram), will not have SNB nor margin status as piecemeal excision so also evaluates if it is safe to OMIT SNB as they do not get SNB. They must have Radiotherapy and recall that similar patient group may get WLE and no Radiotherapy as part of **PRIMETIME II**.

RAFAELO

- RFA use in T1 low grade tumours.

FROST and ICE3

- Both exploring the use of cryo ablative techniques in screen detected low grade T1 tumours [interim report from ICE3 is available].

MIAMI (planned completion 2020, not yet reported)

- Therapeutic Mammo versus Mastectomy in multifocal breast ca - struggled to recruit.

De-Escalation Axilla

POSNOC and ATNEC and ALLIANCE 1102

- Upfront = POSNOC -adjuvant patients give or avoid treatment of axilla - Any age T1-3, 1-2 +ve SNB, AND receiving adjuvant systemic therapy. Planned stratification. Estimated 2026.
- NAC with now negative node = ATNEC - RCT evaluating axillary treatment post-neoadjuvant chemo in patients w/ no residual disease (ypN0) on sentinel node biopsy/TAD when prior were T1-3 N1 M0. Randomized to therapy or none of axilla, with options for Radiotherapy or ANC as treatment.
- NAC with low burden = ALLIANCE 1102 - T1-3 N1 then NAC clinically negative axilla but TAB/SNB +ve randomized to axillary surgery and nodal Radiotherapy OR no surgery but both Axillary Radiotherapy and nodal Radiotherapy. Current standard is to offer ANC to positive post NAC axilla.