Figure 1  Study Flow Chart

ICF for patients with unknown BRCA status to undergo central BRCA testing during, or prior to, neoadjuvant/adjuvant chemotherapy

Neoadjuvant chemotherapy
Minimum 6 cycles (containing anthracyclines, taxanes or the combination of both)

Surgery

Path CR
For TNBC: Non-Path CR
For ER and/or PgR\(^+\) HER2\(^-\); Non-Path CR AND CPS\&EG score ≥ 3

Not eligible

Surgery

Adjuvant Chemotherapy
Minimum 6 cycles (containing anthracyclines, taxanes or the combination of both)

Radiotherapy/additional surgery as required

Informed consent for participation in the study for patients with known gBRCA mutation status

Randomisation
(ideally within 8 weeks after last treatment (surgery, chemotherapy or radiotherapy), but in no case longer than 12 weeks)

Olaparib 300 mg orally twice daily, continuous for 12 months
OR
Placebo orally twice daily, continuous for 12 months

Mammogram and/or breast MRI 6 months from day 1

Follow up for local and distant recurrence and survival status
Patients will continue to be followed clinically on a 3 monthly basis during the first 2 years, followed by 6 monthly assessments for the 3rd, 4th and 5th year, and annually thereafter.

Yearly breast imaging (mammogram and/or MRI) for 10 years*

*The study will end 10 years after the last patient has been randomised
Figure 2  Screening Plan

Screening PART 1 – Patients with Unknown gBRCA Mutation Status:

- Only those patients who do not know their gBRCA mutation status prior to entry into the study

These patients will undergo screening assessments as described for PART 1 in Table 1. Screening PART 1 is conducted to determine if the patient is considered eligible to undergo the BRCA status blood test. Once PART 1 has been successfully completed and patients have had a BRCA test, these patients will continue to PART 2 and have all procedures performed as described for PART 2 (see Table 1).

Screening – PART 2 – ALL Patients (Patients with Known gBRCA Mutation Status):

- Those patients who already know their gBRCA mutation status and have a deleterious or suspected deleterious mutation to undergo screening assessments as described for PART 2 (see Table 1)

- Those patients originally with unknown gBRCA status who have completed screening PART 1 and now have a confirmed deleterious or suspected deleterious mutation should undergo screening assessments as described for PART 2 (see Table 1)