

Participant Trial Number:

To randomise, please complete this form and contact Warwick Clinical Trials Unit
Mon-Fri 09:00-17:00 via telephone 02476 150402 or fax this form to 02476 151586.

2.1 SITE DETAILS

Site: Randomising investigator: (individual who obtained consent)

2.2 CALLER'S DETAILS

Name: Telephone: Fax:

2.3 PARTICIPANT DETAILS

1. Participant initials:

2. Gender: Female Male

3. Date of birth: - -

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4. NHS/CHI/HSCN number:

5. Has the patient been treated with pre-surgical endocrine therapy? Yes No

If YES a pre-treatment core biopsy must be sent to the Central Laboratory.

2.4 STRATIFICATION (please select one answer for each question)

1. Invasive tumour size: < 30mm ≥ 30mm

2. Histological grade: Grade 1 Grade 2 Grade 3

For questions 1 to 3: If the participant has multiple ipsilateral please record details of tumour with the highest NPI score. See form completion guidance for formula to calculate NPI.

3. Number of involved nodes:

Node negative (includes Isolated Tumour Cells only)

Positive sentinel node biopsy with micrometastases only and no axillary clearance

Positive sentinel node biopsy with macrometastases and no axillary clearance

1-3 involved nodes with axillary clearance (count both micrometastases and macrometastases) ...

4-9 involved nodes with axillary clearance (count both micrometastases and macrometastases) ...

4. Intended chemotherapy regimen:

(F)EC75-80 E-CMF (F)EC-T dd AC/EC-P

(F)EC90-100 TC (F)EC-Pw/P2w TAC

5. Menopausal status:

Male

Postmenopausal

Premenopausal → **If premenopausal, state intended endocrine therapy:**

Tamoxifen + ovarian suppression

Aromatase inhibitor + ovarian suppression

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2.5 PARTICIPANT ELIGIBILITY (answers must fall in unshaded boxes)

No Yes

1. Has a designated individual* completed and signed an Eligibility Form?
(*Randomising investigator, i.e. individual who obtained consent)

2. Does the participant meet all of the eligibility criteria?

2.6 PARTICIPANT CONSENT FOR OPTIMA (answers must fall in unshaded boxes)

No Yes

1. Has the participant given written informed consent to be randomised?

2. Have all the fields on the consent form been completed correctly?

3. Has the participant consented to donate the remainder of their sample to future research?

4. Has the participant consented to be contacted regarding future studies?

5. Date consent form signed by participant:

- -

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2.7 QUALITATIVE RECRUITMENT STUDY (QRS)

1. Has the participant consented to have their consultations about the study audio-recorded?

No, participant not approached

No, participant declined

Yes → If Yes, provide following details:

Date audio-recording consent form signed by participant:

- -

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How many audio-recordings were made with the participant?

Form completed by

Printed name:

Signature:

Date signed:

- -

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N.B. The individual named must be on the delegation log with the assigned responsibility to perform randomisation.

TO BE COMPLETED BY SITE AFTER RANDOMISATION

(please also record the Participant Trial Number in the form header on Page 1)

PARTICIPANT TRIAL NUMBER:

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2.1. SITE DETAILS

Completion Guidelines for CRF 2 - Randomisation Form

Randomising investigator

This is the trial investigator who counter-signed the participant's consent form. This individual's name must be on the Site Signature and Delegation Log with the assigned responsibility to obtain informed consent.

2.2. CALLER'S DETAILS

Caller's name

This will be the person the randomisation confirmation fax and email will be sent to and to whom queries regarding the randomisation will be directed. This individual's name must be on the Site Signature and Delegation Log with the assigned responsibility to perform randomisation.

2.3. PARTICIPANT DETAILS

Participant initials

Write the initials of the participant's first/given name, middle name and surname/family name. If no middle name place dash ("-") in middle box.

Date of birth

Please use the following format for dates: 06-Jun-1956.

Has the patient been treated with pre-surgical endocrine therapy?

If yes, a pre-treatment core biopsy **must** be sent to the Central Laboratory for processing; a sample from a surgical excision or other on-treatment biopsy is not acceptable. Refer to the Protocol / Site Sample Collection SOP for further guidance.

2.4. STRATIFICATION

Questions 1 to 3

If the participant has multiple ipsilateral tumours which meet the inclusion criteria please record details of the tumour with the highest Nottingham Prognostic Index (NPI) score. NPI score is calculated using the following formula:

$$\text{NPI Score} = (0.2 \times \text{Invasive tumour size}) + \text{Grade} + \text{Nodal status}$$

Where:

- Invasive tumour size is measured in cm
- Grade is the histological grade: Grade 1 = Score 1 | Grade 2 = Score 2 | Grade 3 = Score 3
- Nodal status: No positive nodes = Score 1 | 1-3 positive nodes = Score 2 | ≥ 4 positive nodes = Score 3

Examples:

For a 30mm Grade 2 carcinoma with 2 nodes positive the NPI = 4.6 (Derived from $[0.2 \times 3.0] + 2 + 2$)

For an 8mm Grade 3 carcinoma with 2 nodes positive the NPI = 5.16 (Derived from $[0.2 \times 0.8] + 3 + 2$)

If both of these tumours are in the same breast record the details of the 8mm Grade 3 carcinoma as this has the higher score

Please note when calculating the NPI Score:

*In practice, nodal status can be ignored as this is the same for all tumours in the breast
Use size of invasive tumour (diameter excluding DCIS) not total tumour size.*

Menopausal status

Women who fulfil the following criteria at trial entry will be considered postmenopausal:

- Age >45 and natural amenorrhoea of at least 1 year's duration
- Bilateral surgical oophorectomy
- For amenorrhoea not fulfilling the above criteria the diagnosis of postmenopausal status should be supported by hormone measurement: FSH levels must be $> 25\text{IU/L}$ with low oestradiol (i.e. within the locally defined postmenopausal range), in the event of doubt measured on 2 occasions preferably 4-6 weeks apart. This applies to women who have undergone hysterectomy without bilateral surgical oophorectomy and are age <60 ; those ≥ 60 may be considered postmenopausal. Women who do not fulfil the above criteria (and those who develop post-chemotherapy amenorrhoea) should be considered to be premenopausal.

Please note: hormonal contraception will suppress FSH and oestradiol levels. In those taking oral contraception, levels will recover rapidly on discontinuation. Depo-Provera injectable contraception lasts many months: all such women should be considered premenopausal.

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