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CANDO-3: Body composition and chemotherapy toxicity in women with early breast cancer

Submission date 08/07/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 27/07/2020	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 04/08/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Some patients with early breast cancer are treated with chemotherapy before or after surgery to remove the tumour from the breast. This chemotherapy is given with the aim of eradicating any cancer cell that have already escaped into the general circulation and therefore reduce the risk of the cancer returning in the future. Chemotherapy treatment in this setting is most effective if patients receive the optimum dose of chemotherapy on time without delays in their treatment or reductions in their chemotherapy doses. Chemotherapy doses are currently calculated from a patient's height and weight. However, these calculations were designed for normal weight patients and this has resulted in uncertainty as to whether obese patients are being dose with chemotherapy correctly. We know that approximately 26% of British women are considered to be obese and that obese breast cancer patients have a higher risk of disease recurrence than healthy-weight patients. A review by the American Society of Oncologists suggested that oncologists may underdose obese patients and our own data suggests that some obese patients may be more at risk of experiencing severe side effects from chemotherapy than healthy weight patients, resulting in treatment delays.

Obesity is defined by body mass index which is also a calculation from height and weight and does not take into account the fact that people of the same size can have different amounts of blood, muscle and fatty tissue which can all affect the behaviour of drugs. Detailed assessments of lean and fat patterns, (body composition), can now be obtained within a few minutes using a technique called bioelectrical impedance analysis (BIA). Our pilot study, CANDO-2, has confirmed that data on the body composition of early breast cancer patients attending routine chemotherapy out-patients can be collected quickly and easily by asking patients to stand on a segmental BIA analyser for a few minutes after they have undergone their usual weight measurement, and that these measurements may help predict when patients might need to unexpectedly return to hospital during chemotherapy for side effects or problems. In this study we will be collecting body composition data from over 300 women receiving routine chemotherapy before or after breast surgery across several hospital sites in the UK. We will collect information for each patient about the chemotherapy drugs and doses they receive and the side effects they experience to investigate how different patterns of body composition affect response to chemotherapy.

Who can participate?
Women aged 18-80 with a diagnosis of early breast cancer, planned to receive greater than four 21-day cycles day cycles of anthracycline or taxane-based combination chemotherapy.

What does the study involve?
Each time the participant attends an oncology clinic prior to each chemotherapy treatment we will ask them to step onto the Seca medial Body Composition Analyser for a bioelectrical impedance test. The participant will also have their grip strength measured each time they come to clinic. Additionally they will be asked to complete short quality of life and lifestyle questionnaires on how they have been feeling in the weeks since the previous visit. These questionnaires will be completed at visit 1 (5 questionnaires), visit 4 (4), the 2- to 6-week follow-up and the 3-month follow-up.
Chemotherapy toxicity assessment will be performed at visits 2-8, (depending on how many chemotherapy cycles), and at follow-ups at week 2-6 and 3 months. The reviewing doctor or specialist nurse will record toxicities from the previous cycle of chemotherapy according to the NCI Common Toxicity Criteria (version 5.0) in a study clinical report form.

What are the possible benefits and risks of participating?
There are no particular risks involved in taking part in this study. The bioelectrical impedance test using the Seca mBCA515 and the measurements of grip strength will be painless but will take approximately 20 minutes to do. The questionnaires will take approximately 20 minutes to complete.
In terms of benefits, we hope this study will help us to understand whether differences in body composition can effect the severity of side effects from chemotherapy that patients experience, or the effectiveness of this treatment for breast cancer. It will not benefit participants personally but it is hoped that the knowledge gained from this project will help improve the care of women with breast cancer in the future.

Where is the study run from?
The study is a University of Southampton study with Southampton as the host site. University Hospital Southampton is the sponsor.

When is the study starting and how long is it expected to run for?
The study opened to recruitment in Southampton on March 16th 2020. It was immediately suspended by the sponsor due to the COVID-19 pandemic. The study has now reopened in Southampton and the other sites are expected to open sequentially over the next 3 months. There will be an 18-month recruitment period for each site. The study will be expected to end in February 2025.

Who is funding the study?
The study has received funding from the World Cancer Research Fund.

Who is the main contact?
Dr Kesta Durkin, k.l.durkin@soton.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-the-structure-of-the-body-and-how-it-affects-treatment-side-effects-cando-3

Contact information

Type(s)

Public

Contact name
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263666

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 263666, RHMCAN1491

Study information

Scientific Title
The CANDO-3 study: Body composition and chemotherapy toxicity in women with early breast cancer

Acronym
CANDO-3

Study objectives
Differences in bioelectrical impedance measures of resistance, reactance and phase angle and /or derived estimates of low FFMi and elevated FMi, are individually and jointly predictive of chemotherapy toxicity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/01/2020, Hampshire B ethics committee (Level 3 Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8054; hampshireb.rec@hra.nhs.uk), ref: 19/SC/0596

Study design
A multi-centre observational (non-interventional) investigator-led academic prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Current interventions as of 26/04/2023:
At diagnosis 300 women with early breast cancer will be recruited from across several hospital sites and studied prior to, during and after chemotherapy treatment. All patients will be consented prior to their first chemotherapy treatment and receive chemotherapy regimens and usual care as determined by their attending physician using current best practice guidelines to prescribing.

Body composition and impedance measures (resistance, reactance and Phase Angle will be assessed using a phase-sensitive 8-electrode segmental Bioelectrical Impedance Analysis (sBIA) device (Seca medical Body Composition Analyser 515 [mBCA]) prior to each cycle of chemotherapy (4-8 visits and at follow-ups 2-6 weeks and 3 months). Grip strength will also be tested at each study visit. Body composition will also be determined, where available from analysis of staging CT scans (where performed as part of routine clinical care.

Chemotherapy side effects will be recorded according to the NCI Common Toxicity Criteria (version 5.0, Nov 17). In those receiving neo-adjuvant chemotherapy, pathological complete response (pCR) rates will be determined.

Previous interventions as of 23/09/2021 to 09/11/2021:
At diagnosis 300 women with early breast cancer will be recruited from across several hospital sites and studied prior to, during and after chemotherapy treatment. All patients will be consented prior to their first chemotherapy treatment and receive chemotherapy regimens and usual care as determined by their attending physician using current best practice guidelines to prescribing.

Body composition and impedance measures (resistance, reactance and Phase Angle will be assessed using a phase-sensitive 8-electrode segmental Bioelectrical Impedance Analysis (sBIA) device (Seca medical Body Composition Analyser 515 [mBCA]) prior to each cycle of chemotherapy (4-8 visits and at follow-ups 2-6 weeks and 3 months). Grip strength will also be tested at each study visit. Body composition will also be determined, where available from analysis of staging CT scans (where performed as part of routine clinical care.

Chemotherapy side effects will be recorded according to the NCI Common Toxicity Criteria (version 5.0, Nov 17). In those receiving neo-adjuvant chemotherapy, pathological complete response (pCR) rates will be determined.

In the Southampton mechanistic optional sub-study only, body composition will be also determined by Dual-energy x-ray absorptiometry (DXA) and bloods will be taken for further analysis.

Previous interventions as of 23/09/2021:
At diagnosis 300 women with early breast cancer will be recruited from across 7 hospital sites and studied prior to, during and after chemotherapy treatment. All patients will be consented prior to their first chemotherapy treatment and receive chemotherapy regimens and usual care as determined by their attending physician using current best practice guidelines to prescribing.

Body composition and impedance measures (resistance, reactance and Phase Angle will be assessed using a phase-sensitive 8-electrode segmental Bioelectrical Impedance Analysis (sBIA) device (Seca medical Body Composition Analyser 515 [mBCA] prior to each cycle of chemotherapy (4-8 visits and at follow-ups (3 weeks and 3 months. Grip strength will also be tested at each study visit. Body composition will also be determined, where available from analysis of staging CT scans (where performed as part of routine clinical care.

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routine clinical care.

Chemotherapy side effects will be recorded according to the NCI Common Toxicity Criteria (version 5.0, Nov 17). In those receiving neo-adjuvant chemotherapy, pathological complete response (pCR) rates will be determined.

In the Southampton mechanistic optional sub-study only, body composition will be also determined by Dual-energy x-ray absorptiometry (DXA). Peak VO2 and Anaerobic Threshold (AT) will be determined by cardiopulmonary exercise testing (CPET) and bloods will be taken for further analysis.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 09/11/2021:
At every study visit prior to each cycle of chemotherapy (4-8 visits) and at follow-ups (2-6 weeks and 3 months):
1. FMi determined by sBIA using the Seca mBCA 515
2. Chemotoxicity reporting according to the NCI Common Toxicity Criteria (version 5.0, Nov 17)

Previous primary outcome measure:
At every study visit prior to each cycle of chemotherapy (4-8 visits) and at follow-ups (3 weeks and 3 months):
1. FMi determined by sBIA using the Seca mBCA 515
2. Chemotoxicity reporting according to the NCI Common Toxicity Criteria (version 5.0, Nov 17)

Secondary outcome measures
Current secondary outcome measures as of 26/04/2023:
At every study visit prior to each cycle of chemotherapy (4-8 visits) and at follow-ups (2-6 weeks and 3 months) unless otherwise stated:
1. Grip strength using JAMAR hydraulic hand dynamometer at every study visit
2. sBIA to measure bioelectrical properties and body composition using the Seca mBCA 515 at every study visit
3. Quality of life and lifestyle using validated questionnaires: At visit 1: AUDIT-C, EORTC QLQC30, EORTC QLQ-BR23, IPAQ-SF and CNAQ. At visit 4, and at follow-ups 3 weeks and 3

months: EORTC QLQ-C30, EORTC QLQ-BR23, IPAQ-SF and CNAQ
4. Chemotoxicity assessments according to the standardised NCTAE v5.0 criteria: At every study visit (APART FROM VISIT 1)
5. If and when clinically indicated body composition by sliceomatic analysis from routine care CT scans: This would usually be prior to commencement of chemotherapy but timings may be variable.

Previous secondary outcome measures as of 23/09/2021 to 09/11/2021:
At every study visit prior to each cycle of chemotherapy (4-8 visits) and at follow-ups (2-6 weeks and 3 months) unless otherwise stated:
1. Grip strength using JAMAR hydraulic hand dynamometer at every study visit
2. sBIA to measure bioelectrical properties and body composition using the Seca mBCA 515 at every study visit
3. Quality of life and lifestyle using validated questionnaires: At visit 1: AUDIT-C, EORTC QLQ-C30, EORTC QLQ-BR23, IPAQ-SF and CNAQ. At visit 4, and at follow-ups 3 weeks and 3 months: EORTC QLQ-C30, EORTC QLQ-BR23, IPAQ-SF and CNAQ
4. Chemotoxicity assessments according to the standardised NCTAE v5.0 criteria: At every study visit (APART FROM VISIT 1)
5. If and when clinically indicated body composition by sliceomatic analysis from routine care CT scans: This would usually be prior to commencement of chemotherapy but timings may be variable

As part of the optional Southampton mechanistic sub-study only:
6. Body composition by DXA using a Lunar Hologic scanner at visit 1 and at End of Study visit
7. One blood sample taken for biobanking at visit 1, visit 4, and at follow-ups 3 weeks and 3 months

Previous secondary outcome measures as of 23/09/2021:
At every study visit prior to each cycle of chemotherapy (4-8 visits) and at follow-ups (3 weeks and 3 months) unless otherwise stated:
1. Grip strength using JAMAR hydraulic hand dynamometer at every study visit
2. sBIA to measure bioelectrical properties and body composition using the Seca mBCA 515 at every study visit
3. Quality of life and lifestyle using validated questionnaires: At visit 1: AUDIT-C, EORTC QLQ-C30, EORTC QLQ-BR23, IPAQ-SF and CNAQ. At visit 4, and at follow-ups 3 weeks and 3 months: EORTC QLQ-C30, EORTC QLQ-BR23, IPAQ-SF and CNAQ
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7. One blood sample taken for biobanking at visit 1, visit 4, and at follow-ups 3 weeks and 3 months

Previous secondary outcome measures:
At every study visit prior to each cycle of chemotherapy (4-8 visits) and at follow-ups (3 weeks and 3 months) unless otherwise stated:
1. Grip strength using JAMAR hydraulic hand dynamometer at every study visit
2. sBIA to measure bioelectrical properties and body composition using the Seca mBCA 515 at

every study visit
3. Quality of life and lifestyle using validated questionnaires: At visit 1: AUDIT-C, EORTC QLQ-C30, EORTC QLQ-BR23, IPAQ-SF and CNAQ. At visit 4, and at follow-ups 3 weeks and 3 months: EORTC QLQ-C30, EORTC QLQ-BR23, IPAQ-SF and CNAQ
4. Chemotoxicity assessments according to the standardised NCTAE v5.0 criteria: At every study visit (APART FROM VISIT 1)
5. If and when clinically indicated body composition by sliceomatic analysis from routine care CT scans: This would usually be prior to commencement of chemotherapy but timings may be variable

As part of the optional Southampton mechanistic sub-study only:
6. Body composition by DXA using a Lunar Hologic scanner at visit 1 and at End of Study visit
7. Anaerobic threshold and peak VO2 using the LoveMedical ErgostikTM CPET System at visit 1 and at End of Study visit
8. One blood sample taken for biobanking at visit 1, visit 4, and at follow-ups 3 weeks and 3 months

Overall study start date
01/03/2019

Completion date
31/05/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/04/2023:
1. Early invasive breast carcinoma
2. Stage I-III disease
3. Tumour grade, ER and HER 2 status available
4. Clinical or pathological tumour size and lymph node status available
5. Neo-adjuvant or adjuvant systemic chemotherapy recommended by local breast multidisciplinary meeting
6. No prior systemic anti-cancer treatment within the past 10 years (hormonal therapy started since current breast cancer diagnosis (e.g. neoadjuvant or bridging endocrine therapy allowed)
7. No evidence of distant metastatic disease
8. Patient agrees to receive neo/adjuvant chemotherapy
9. Planned to receive greater than 4 x 21-day cycles of anthracycline or taxane-based combination chemotherapy. 21-day combination regimens including weekly treatments are allowed e.g. 1. carboplatin D1/paclitaxel D1, D8, D15 2. EC-weekly paclitaxel. Patients planned to receive the anthracycline component of the chemotherapy regimen at 2-weekly intervals (accelerated regimens) are additionally eligible for inclusion
10. Aged ≥18 years and <80 years
11. Female
12. Able to complete written records in English

Previous inclusion criteria as of 27/07/2021 to 24/08/2021:
1. Early invasive breast carcinoma
2. Stage I-III disease
3. Tumour grade, ER and HER 2 status available
4. Clinical or pathological tumour size and lymph node status available

5. Neo-adjuvant or adjuvant systemic chemotherapy recommended by local breast multi-disciplinary meeting
6. No prior systemic anti-cancer treatment within the past 10 years
7. No evidence of distant metastatic disease
8. Patient agrees to receive neo/adjuvant chemotherapy
9. Planned to receive greater than 4 x 21-day cycles of anthracycline or taxane-based combination chemotherapy. 21-day combination regimens including weekly treatments are allowed e.g. 1. carboplatin D1/paclitaxel D1, D8, D15 2. EC-weekly paclitaxel
10. Aged ≥18 years and <80 years
11. Female
12. Able to complete written records in English

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1. Early invasive breast carcinoma
2. Stage I-III disease
3. Tumour grade, ER and HER 2 status available
4. Clinical or pathological tumour size and lymph node status available
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6. No prior systemic anti-cancer treatment
7. No evidence of distant metastatic disease
8. Patient agrees to receive neo/adjuvant chemotherapy
9. Planned to receive greater than 4 x 21-day cycles of anthracycline or taxane-based combination chemotherapy. 21-day combination regimens including weekly treatments are allowed e.g. 1. carboplatin D1/paclitaxel D1, D8, D15 2. EC-weekly paclitaxel
10. Aged ≥18 years and <80 years
11. Female
12. Able to complete written records in English

Previous inclusion criteria:
1. Early invasive breast carcinoma
2. Stage I-III disease
3. Tumour grade, ER and HER 2 status available
4. Clinical or pathological tumour size and lymph node status available
5. Neo-adjuvant or adjuvant systemic chemotherapy recommended by local breast multi-disciplinary meeting
6. No prior systemic anti-cancer treatment
7. No evidence of distant metastatic disease
8. Patient agrees to receive neo/adjuvant chemotherapy
9. Planned to receive 4-6 21 day cycles of anthracycline or taxane-based combination chemotherapy
10. Aged ≥18 years and <80 years
11. Female
12. Able to complete written records in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Female

Target number of participants
300

Total final enrolment
300

Key exclusion criteria
Current participant exclusion criteria as of 11/02/2022:
1. Previous invasive malignancy (with the exception of non-melanomatous skin cancer) within the past 10 years
2. Any other medical conditions preventing physical participation in the study procedures
3. Patients receiving only single agent or weekly neo/adjuvant chemotherapy regimens e.g. weekly paclitaxel with trastuzumab
4. Patients with existing conditions known to affect body water or cause oedema or muscle conditions that may affect muscle mass such as muscular dystrophies
5. Pregnancy
6. Pacemakers

Previous exclusion criteria as of 24/08/2021: :
1. Previous invasive malignancy (with the exception of non-melanomatous skin cancer) within the past 10 years
2. Any other medical conditions preventing physical participation in the study procedures
3. Patients receiving only single agent or weekly neo/adjuvant chemotherapy regimens e.g. weekly paclitaxel with trastuzumab
4. Patients with existing conditions known to affect body water or cause oedema or muscle conditions that may affect muscle mass such as muscular dystrophies
5. Pregnancy

Previous exclusion criteria as of 27/07/2021:
1. Previous invasive malignancy (with the exception of non-melanomatous skin cancer)
2. Any other medical conditions preventing physical participation in the study procedures
3. Patients receiving only single agent or weekly neo/adjuvant chemotherapy regimens e.g. weekly paclitaxel with trastuzumab
4. Patients with existing conditions known to affect body water or cause oedema or muscle conditions that may affect muscle mass such as muscular dystrophies
5. Pregnancy

Previous exclusion criteria:
1. Previous invasive malignancy (with the exception of non-melanomatous skin cancer)
2. Any other medical conditions preventing physical participation in the study procedures
3. Patients receiving single agent or weekly neo/adjuvant chemotherapy regimens e.g. weekly paclitaxel with trastuzumab

4. Patients with existing conditions known to affect body water or cause oedema or muscle conditions that may affect muscle mass such as muscular dystrophies
5. Pregnancy

Date of first enrolment
16/03/2020

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salisbury District Hospital
Salisbury NHS Foundation Trust
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals NHS Trust
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
The Christie Hospital
The Christie NHS Foundation Trust
Department of Medical Oncology – Breast Team
Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre

Royal Devon and Exeter NHS Foundation Trust
Royal Devon and Exeter NHS Foundation Trust
Barrack Road
Exeter
EX2 5DW
Exeter
United Kingdom
EX2 5DW

Study participating centre
Churchill Hospital
Oxford University Hospitals NHS Foundation Trust
Old Road
Oxford
United Kingdom
OX3 7LE

Study participating centre
Royal Cornwall Hospital
Royal Cornwall Hospitals NHS Trust
Treliske
Truro, Cornwall
United Kingdom
TR1 3LJ

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

Sponsor details
R&D Department
E level, SCBR, MP 138

Southampton General Hospital
Southampton
England
United Kingdom
SO16 6YD
+44 (0)23 81205664
sponsor@uhs.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
World Cancer Research Fund International

Alternative Name(s)
WCRF International, WCRF

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The chief and co-investigators will be responsible for publication of the study findings in a peer-reviewed journal, on behalf of all collaborators. The manuscript will be prepared by a writing group, and participating investigators will be selected to join the writing group on the basis of contribution and following standard protocols for authorship. All participating clinicians will be acknowledged in the publication.

A statement thanking study participants for their participation will be included in the study publication. Manuscripts, abstracts and publications will also include an acknowledgement of funding bodies. The University Hospital Southampton NHS Trust Foundation (UHS) and University of Southampton will appear as affiliates in all submissions and publications.

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Prof Ramsey Cutress via Dr Kesta Durkin.
Anonymous data will be available for request from three months after publication of the article until the end of the archive and storage period described below. It will be available to researchers who provide a completed Data Sharing request form that describes a methodologically sound proposal, for the purpose of the approved proposal and if appropriate, signed a Data Sharing Agreement. Proposals will be reviewed by the study steering committee. Data will be shared once all parties have signed relevant data sharing documentation, covering the study steering committee conditions for sharing and if required, an additional Data Sharing Agreement from Sponsor. Proposals should be directed to the chief investigator.
Following the close of the study, collection, analyses and reporting of data, the research data generated by this study will be archived and stored for 15 years in line with the Data Protection procedures that govern all research at the University of Southampton: data will be collected and retained in accordance with the General Data Protection Regulations 2018 in compliance with Caldicott principles.
Point 9 of the CANDO-3 study participant consent form states: “I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers”.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/02/2022	20/09/2022	Yes	No
HRA research summary			28/06/2023	No	No