ISRCTN50261938 https://doi.org/10.1186/ISRCTN50261938

Study to evaluate treatment efficacy by monitoring minimal residual disease in an early breast cancer population

Submission date 06/04/2023	**Recruitment status** Suspended	[X] Prospectively registered [_] Protocol
Registration date 22/09/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 21/01/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to evaluate the effectiveness of anticancer treatments by monitoring the number of cancer cells left in the body after treatment.

Who can participate?
Patients aged ≥18 years with early-stage HR-positive/HER2-negative breast cancer at high risk of relapse but with no evidence that the cancer has spread

What does the study involve?
Patients will first enter a surveillance phase. Blood will be collected periodically to monitor the absence or presence of circulating tumour DNA (ctDNA) in the bloodstream whilst participants continue to take ET as prescribed. If the ctDNA result turns positive, then patients will be screened to enter the treatment phase. The number of visits is between 7-14 over about 1-5 years. Blood samples will be taken every 3 months during the first year and every 6 months from the second year. Upon confirmed positive ctDNA, the participant will be allocated to one of four treatment arms. This can include either the control arm where participants will continue taking the same ET as previously prescribed or a medication called giredestrant, either as monotherapy (on its own) or in combination with abemaciclib or inavolisib. Apart from abemaciclib, the study drugs are not yet approved by the MHRA. In preclinical studies, giredestrant and inavolisib showed strong anti-tumour activity. Participants will receive study treatment every day from Day 1, continuously in cycles of 28 days for 2-5 years. Participants may continue to receive study drugs for a prolonged period. Once the treatment is complete, participants will have a safety follow-up visits. The following study procedures will be performed during the treatment phase: physical examinations, ECGs, blood tests, urine tests, CT/MRI/bone scans, ultrasound, and mammogram.

What are the possible benefits and risks of participating?
All risks and burdens will be discussed in detail with each participant during the informed consent process and will be stipulated in the participant information sheet. Opportunities to discuss and address it further will be offered throughout the trial. An independent committee of

experts will review the continued safety of the study drugs and will swiftly act on any concerns. Giredestrant and inavolisib are experimental medications; therefore, the risks and discomforts related to these drugs are not known, and there may be side effects no one knows about yet. Abemaciclib is a registered medication with marketing authorisation, but not all the side effects of abemaciclib when used alone or when given with other drugs are known. Participants will be monitored carefully. Abemaciclib treatment may be temporarily interrupted in patients who experience toxicity considered related to the study drug. In the event of multiple toxicities, dose interruption should be based on the worst toxicity observed. To date, available information from these studies has suggested that giredestrant does not cause serious side effects. Safety information for giredestrant is still limited at this time, and unforeseen risks may occur. Participants will be given medicines to help lessen the main side effects and encouraged to contact their medical doctor immediately for any observed side effects. Some side effects may be serious and may even result in death.

Based on the anti-estrogenic pharmacological activity of giredestrant, administration of giredestrant during pregnancy is expected to have an adverse effect and poses a risk to the human foetus, including birth defects and miscarriage. For participants on inavolisib: patients at risk for developing hyperglycemia may initiate oral type 2 diabetes medication where allowed by local regulations. In addition, any patient may be instructed to utilise a glucometer to monitor fasting glucose at home daily. It is unknown whether the IMPs might affect an unborn child therefore, WOCBP will be informed of potential risks associated with pregnancy and will be offered options to avoid pregnancy. Breach of confidentiality may be a concern therefore, a participant will only be identified by means of a participant identification number and their identity will never be disclosed. Risk of incurring additional costs will be addressed by assuring the participant that all extra costs will be covered by the sponsor.

Blood collection might cause pain, and there is a small risk of bleeding, bruising, or infection at the place where the needle is inserted. Rarely do some people experience dizziness, upset stomach, or fainting.

The radiation exposure from the CT scan is low and is not likely to adversely affect patients. However, the effects of radiation add up over a lifetime. The doctor may wish to use contrast agents, referred to as “dyes,” to increase visibility. The use of intravenous contrast during a CT scan can be associated with a warm, flushed sensation during the injection and a metallic taste in the mouth. It could also cause allergic reactions, decreased kidney function, and in very rare cases, anaphylactic shock (low blood pressure, loss of consciousness, and severe loss of body fluid that can lead to shock or death). CT scans are a necessary part of this study with the aim of assessing the course of the disease.

Alternatively, the doctor may evaluate the abdomen and pelvis by MRI. An MRI scanner uses electromagnetic radiation (radio waves) in a strong magnetic field. Some people may become anxious or experience discomfort in the confined space of an MRI scanner. If participants do experience discomfort at any time during the scan, they will be able to alert the staff by pressing on a call button provided. There are no proven long-term risks related to MRI scans as used in this research study. An MRI is considered safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so metal objects mustn’t be taken into the scanner room.

Bone scans (or bone scintigraphy) use radionuclides containing radioactivity called gamma rays. A controlled amount of radiopharmaceutical will be used to minimise exposure. For the electrocardiogram participants will have adhesive patches placed on the chest, arms, and legs. In some areas, it may be necessary to shave a small spot. After an ECG, participants may have mild irritation, slight redness, and itching at the places on their skin where the recording patches are placed. Some risks are unknown or do not often happen when participants take the study drug. Participants will be informed in a timely manner of any new information, findings, or changes.

Where is the study run from?
Medica Scientia Innovation Research, S.L. (MEDSIR) (Spain)

When is the study starting and how long is it expected to run for?
April 2023 to June 2028

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
info@medsir.org

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-a-blood-test-to-monitor-for-early-signs-of-breast-cancer-coming-back-mirador

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2022-002616-24

IRAS number
1007314

ClinicalTrials.gov number
NCT05708235

Secondary identifying numbers
MEDOPP485, IRAS 1007314, CPMS 55251

Study information

Scientific Title
A proof of concept study to evaluate treatment efficacy by monitoring minimal residual disease using ctDNA in a HR-positive/HER2-negative early breast cancer population

Acronym
MiRaDoR

Study objectives
Primary objective:
To evaluate the efficacy in terms of rate of patients with a 90% decrease or clearance in baseline ctDNA at 3 months of the different arms.

Secondary objectives:
Surveillance phase:
1. To assess the incidence of ctDNA detection in patients with HRpositive/HER2-negative BC

Treatment phase:
1. To evaluate the efficacy in terms of:
1.1. A 90% decrease in baseline ctDNA at 6, 9, and 12 months of the experimental arms
1.2. A 90% decrease in baseline ctDNA at 3 months and maintained at 6 months and 12 months of the different arms
1.3. A 50% and 70% decrease in baseline ctDNA at 3, 6, 9 and 12 months of the different arms
1.4. Time to rising ctDNA during the study follow-up of the different arms
1.5. Time with at least a 90% decrease in baseline ctDNA of the different arms

2. To evaluate the ctDNA decrease relative to baseline at 3, 6, 9 and 12 months of the different arms
3. To evaluate the safety and tolerability of the different treatments

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/08/2023, North West - Liverpool Central Research Ethics Committee (3rd Floor, Barlow House, HRA NRES Centre, Manchester , M1 3DZ, United Kingdom; +44 (0)2071048118; liverpoolcentral.rec@hra.nhs.uk), ref: 23/EM/0098

Study design
Multicentre open-label non-comparative Phase II trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Early breast cancer

Interventions
This trial is a multicentre, open-label, non-comparative, Phase II, biomarker-driven adjuvant treatment study involving the periodic collection and analysis of blood samples from patients with HR-positive/HER2-negative early-stage BC at higher risk of relapse, who have undergone surgery within the previous 5 years, with no evidence of locoregional, contralateral, or distant disease.

The study design is composed of an initial pre-screening phase, a molecular follow-up phase (ctDNA surveillance phase), and an interventional therapeutic phase (treatment phase).

After informed consent is obtained, an estimated total of 1,260 eligible patients will enter a ctDNA surveillance in which primary tumour tissue and matched normal blood will be collected from each patient to obtain a patient-specific somatic mutations panel (tumour signature).

At the event of ctDNA positivity, patients will be screened to enter the treatment phase of the study. Upon confirmed eligibility, a total of 40 patients will be allocated in one of the following trial's arms adopting a sequential recruitment strategy:

Arm A: Control Arm (n = 10)
Patients must continue the same standard ET, prescribed as per standard practice, used in the surveillance phase. Changes in ET are not allowed.

Arm B: Experimental Arm with giredestrant (n = 10)
Giredestrant: 30 mg will be administered PO QD on Days 1 to 28 of each 28-day cycle up to 5 years or until disease recurrence, unacceptable toxicity, or treatment/study discontinuation (whichever occurs first).

Arm C: Experimental Arm with giredestrant + abemaciclib (n = 10)
Giredestrant: 30 mg will be administered PO QD on Days 1 to 28 of each 28-day cycle up to five years or until disease recurrence, unacceptable toxicity, or treatment/study discontinuation (whichever occurs first).
Abemaciclib 150 mg will be taken PO BID (two intakes for a total daily dose of 300 mg) during each 28-day cycle up to 2 years or until disease recurrence, unacceptable toxicity, or treatment /study discontinuation (whichever occurs first).

Arm D: Experimental Arm with giredestrant + inavolisib (n = 10)
Giredestrant: 30 mg will be administered PO QD on Days 1 to 28 of each 28-day cycle up to 5 years or until disease recurrence, unacceptable toxicity, or treatment/study discontinuation (whichever occurs first).
Inavolisib: 9 mg will be administered PO QD on Days 1 to 28 of each 28-day cycle up to 2 years or until disease recurrence, unacceptable toxicity, or treatment/study discontinuation (whichever occurs first).
If the strategy of ctDNA monitoring enables physicians to identify patients at high risk of relapse and assess whether treatment at molecular relapse can improve outcome, new cohorts may be added to the study.
Note I: In addition to the treatments described on each of the treatment arms, LHRH agonist will be administered to male participants and premenopausal/perimenopausal participants according to local prescribing information. The patient should be supplied with the previous LHRH they were taking.
Note II: During the length of the study, additional treatment arms may open to stay up to date with the most recent advances in oncology, and to be able to provide the best treatment options to patients in this study. Because of that, the N of patients screened to enter the treatment phase may increase.
In the meanwhile, serial assessment of ctDNA will be continuously performed every three months during the first year and every 6 months thereafter until EoS (End of Study) to correlate any ctDNA variations with response.
Patients discontinuing the study treatment period will enter a post-treatment follow-up period during which survival and new anti-cancer therapy information will be collected every three months (±14 days) from the last dose of study treatment up to the EoS.

Arm extensions:
After initiation of study treatments, data obtained from the serial assessment of ctDNA will also be used to confirm the feasibility of eventual arms extensions, with a maximum of two arms that could be expanded (10 additional patients will be enrolled in each of the selected arms). The expansion will be approved when the arm complies with the following criteria:
1. If at 3 months, a 90% ctDNA decrease is observed in at least 30% patients and if after three additional months, a 90% ctDNA decrease is maintained in at least 20% patients In this case, 10 additional patients will be enrolled in the specific experimental arms that meet these requirements (n = 20).

2. If all three experimental arms fulfil the criteria, the two arms with the highest proportion of patients with the highest proportion of 90% decrease will be the ones expanded.
3. If cohorts remain too similar (no clear "winners"), the decision will be taken by the Steering Committee based on the duration of the response and the safety and toxicity of each specific treatment.
4. If none of the arms fulfil the specific expansion criteria, the Steering Committee will evaluate the data further and may nominate the two arms with the strongest signal of ctDNA decreases for further expansion.

Sequential recruitment will be adopted, and the different treatment arms will be filled following order below:
1. Control arm A (for patients with PIK3CAwt tumours, or patients with PIK3CAmut tumours that do not fulfil the specific criteria to enter arm D) and arm D (for patients with PIK3CAmut tumours that fulfil the specific criteria to enter arm D).
2. Once arm A is closed, patients will be included in arm B (for patients with PIK3CAwt tumours, or patients with PIK3CAmut tumours that do not fulfil the specific criteria to enter arm D. Also for patients with PIK3CAmut tumours that fulfil the specific criteria to enter arm D once arm D is completed).
3. Once arms A and B are closed, patients will be included in arm C (for patients with PIK3CAwt tumours, or patients with PIK3CAmut tumours that do not fulfil the specific criteria to enter arm D. Also for patients with PIK3CAmut tumours that fulfil the specific criteria to enter arm D once arm D is completed).
Depending on the number of patients with PIK3CAmut tumours included in arms B and C, up to five more patients with these mutations might be included in these arms depending on the Steering Committee decision.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Giredestrant, inavolisib, abemaciclib

Primary outcome measure
Efficacy measured using a comparison of ctDNA levels, expressed as the proportion of patients with at least a 90% decrease or clearance of the baseline ctDNA ,at 3 months after initiation of study treatment

Secondary outcome measures
Surveillance phase:
Levels of ctDNA determined from plasma every 3 months from study inclusion during the first year and every 6 months thereafter until positive result or end of the adjuvant hormonal treatment or end of accrual of the treatment phase.

Treatment phase:
1. The proportion of patients with at least a 90% decrease in baseline ctDNA, calculated using plasma taken at 6, 9, and 12 months after initiation of study treatment
2. The proportion of patients with at least a 90% decrease in baseline ctDNA at 3 months and maintained, calculated using plasma at 6 months and 12 months after initiation of study

treatment
3. The proportion of patients with 50% and 70% decrease in baseline ctDNA, calculated using plasma taken at 3, 6, 9, and 12 months after initiation of study treatment
4. The time to rising ctDNA levels, defined as time to the first ctDNA increase compared to baseline, measured and documented using ctDNA levels in plasma every 3 months from study inclusion during the first year and every 6 months thereafter until positive result
5. The duration of at least a 90% decrease in baseline ctDNA after initiation of study treatment, determined by monitoring ctDNA levels in plasma every 3 to 6 months
6. The best percentage of ctDNA decrease relative to baseline level, calculated using serum levels at 6, 9, and 12 months after initiation of study treatment
7. The safety and toxicity profile monitored according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events Version 5.0 (NCI-CTCAE v.5.0) at 12 months

Overall study start date
04/04/2023

Completion date
30/06/2028

Eligibility

Key inclusion criteria
Surveillance phase:
1. Signed ICF prior to participation in any study-related activities
2. Male or female patients aged 18 years or older
3. ECOG 0 or 1
4. Histologically proven primary HR-positive according to the updated ASCO/CAP 2020 guidelines and HER2-negative BC as per ASCO/CAP 2018 criteria based on local testing on the most recent analyzed biopsy
5. Patients with high-risk early-stage BC according to at least one of the following criteria:
5.1. If no previous neoadjuvant chemotherapy:
5.1.1. pN2/N3 or
5.1.2. pN1,1. pT3/T4 and/or
5.2. High genomic risk defined as Oncotype Dx Recurrence Score > 25 if postmenopausal;> 20 if pre-menopausal, Prosigna score ≥ 41, Mammaprint high risk category or similar and/or
5.3. Histological grade II/III and proliferation marker Ki67 (Ki67) >20%
5.3.1. If patients have received previous neoadjuvant chemotherapy, they must have had significant residual invasive disease defined as at least one of the following:
5.3.1.1. Residual invasive disease in the breast ypT3 or ypT4 and/or
5.3.1.2. Any macroscopic, ≥2 mm, residual lymph node involvement regardless of primary tumor site involvement (includes no residual disease in the breast)
6. On adjuvant treatment with ET for at least 2 years and no more than four years at the time of study enrolment with an additional three years of ET planned. At least 12 months prior to enrolment on the same ET treatment with AI or tamoxifen (LHRH for pre-menopausal women and men is required). Note: Male and pre-menopausal patients treated with tamoxifen alone are excluded
7. No prior treatment with CDK4/6 inhibitors
8. No prior treatment with fulvestrant
9. Willingness and ability to provide tissue from one archival tumor tissue sample (either from diagnostic biopsy, primary surgery, or where available from a residual disease post-neoadjuvant therapy). Note: Patients with multifocal BC may be enrolled, if archival tissue samples from at

least two tumors are available and after histopathological examination, all tumors meet pathologic criteria for HR-positive and HER2-negative BC
10. Absence of metastatic disease by routine clinical assessment (computed tomography [CT] scan of the thorax and abdomen, and bone scan) confirmed no longer than 3 months prior to study inclusion
11. Patients must have had surgery for their primary BC with documented clear margins (as per local guidelines) within the past 5 years
12. Patients must be able and willing to adhere to study procedures.

Treatment phase:
1. Signed ICF prior to study inclusion
2. ctDNA positivity with no evidence of clinical or radiologic recurrence by standard assessments (e.g. breast ultrasound, staging scans, NMR)
3. ECOG 0, 1 or 2
4. Patients must have received the same ET during at least the last 12 months. A temporary discontinuation of <90 days during the surveillance phase is allowed
5. Receiving LHRH agonist therapy alongside the same ET treatment for at least 90 days prior to initiation of one of the available study treatments if male or pre-menopausal.
6. Female of reproductive potential and male patients with female partners of childbearing potential, must remain abstinent and truly abstain from sexual activity (refrains from heterosexual intercourse) or use locally recognized adequate methods of contraception (described as that with a failure rate <1%) for the duration of trial treatment
7. Resolution of all acute toxic effects of prior anti-cancer therapy to Grade ≤1 as determined by the NCI-CTCAE v 5.0
8. Adequate hematologic and organ function within 14 days before the first study treatment on Day 1 of Cycle 1, defined by the following:
8.1. Hematological (without platelet, red blood cell (RBC) transfusion, and/or granulocyte colony-stimulating factor support within 7 days before first study treatment dose): White blood cell (WBC) count >3.0 x 109/l, absolute neutrophil count (ANC) ≥1.5 x 10e9/l, platelet count ≥100.0 x10e9/l, and hemoglobin ≥9.0 g/dl (≥5.6 mmol/l).
8.2. Hepatic: Serum albumin ≥3 g/dl; Bilirubin ≤ 1.5 times the upper limit of normal (ULN) (≤3 x ULN in the case of Gilbert's disease); aspartate transaminase (AST) and alanine transaminase (ALT) ≤2.5 × ULN; alkaline phosphatase (ALP) ≤2 × ULN.
8.3. Renal: serum creatinine ≤1.5 x ULN or creatinine clearance ≥50 ml/min based on Cockcroft–Gault glomerular filtration rate estimation
9. Participants who are able and willing to swallow, retain, and absorb oral medication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1260

Key exclusion criteria

Surveillance phase:

1. Any concurrent or planned treatment for the current diagnosis of BC other than adjuvant ET
2. Diagnosis of an alternative cancer in the five years prior to primary BC diagnosis other than for nonmelanoma carcinoma of the skin or cervical carcinoma in situ. Other stage I tumors will be discussed case by case prior to inclusion with the Medical Monitor of the study
3. Active or prior documented inflammatory bowel disease (i.e. Crohn's disease, ulcerative colitis, or a preexisting chronic condition resulting in baseline grade ≥1 diarrhea) that may significantly alter the absorption of oral drugs
4. Active cardiac disease or history of cardiac dysfunction including any of the following:
4.1. History (within 2 years from screening) or presence of idiopathic bradycardia or resting heart rate <50 beats per minute at screening
4.2. History of angina pectoris or symptomatic coronary heart disease within 12 months prior to study entry
4.3. QT interval corrected through use of Fridericia's formula (QTcF) >450 ms for women and >470 ms for men by at least three electrocardiograms (ECGs) > 30 minutes apart
4.4. History or presence of an abnormal ECG that is clinically significant in the investigator's opinion
4.5. History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias such as structural heart disease (e.g., severe left ventricular systolic dysfunction, left ventricular hypertrophy cardiomyopathy, infiltrative cardiomyopathy, moderate-to-severe valve disease), coronary heart disease (symptomatic or with ischemia demonstrated by diagnostic testing), clinically significant electrolyte abnormalities (e.g., hypokalemia, hypomagnesemia, hypocalcemia), or family history of long QT syndrome within 12 months
5. History of pneumonitis, ILD, or pulmonary fibrosis
6. Known history of Human Immunodeficiency Virus (HIV) infection (testing not required as part of study screening)
7. Clinically significant liver disease consistent with Child-Pugh C, including active hepatitis (e.g., hepatitis B virus [HBV] or hepatitis C virus [HCV]), current alcohol abuse, cirrhosis, or positive test for viral hepatitis
8. Active bleeding diathesis venous thrombo-embolism, previous history of bleeding diathesis, or chronic anti-coagulation treatment, or any indications or history of Disseminated Intravascular Coagulation (DIC) or DVT. Low molecular weight heparin (LMWH), low-dose aspirin or clopidogrel are permitted
9. Creatinine clearance <30 mL/min
10. Participants with renal dysfunction who require dialysis
11. Patient has any other concurrent severe and/or uncontrolled medical condition that would, in the Investigator' opinion cause unacceptable safety risks, contraindicate patient participation in the clinical trial or compromise compliance with the protocol
12. Females who are known to be breastfeeding or pregnant as determined by a serum pregnancy test human chorionic gonadotropin (β-HCG) prior to the administration of any trial treatment. Since β-HCG overexpression can be also elevated in some tumor types, a positive result should be confirmed with a validated alternative test (e.g., ultrasound)
13. Female or male participants planning a pregnancy

Treatment phase:

1. Known hypersensitivity reaction to any investigational or therapeutic compound or their incorporated substances
2. Undergoing any other simultaneous anti-cancer treatment since enrolling in the study, other than hormonal therapy or a bisphosphonate (or denosumab)
3. Major surgery (defined as requiring general anesthesia) or significant traumatic injury within

28 days of start of study drug, or patients who have not recovered from the side effects of any major surgery
4. Treatment with strong Cytochrome P450 3A4 (CYP3A4) inhibitors or strong CYP3A4 inducers within 14 days or five drug-elimination half-lives, whichever is longer, prior to initiation of one of the available study treatments
5. Patient has a history of non-compliance with medical regimen

Date of first enrolment
05/01/2024

Date of final enrolment
30/07/2025

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Study participating centre
Barts Cancer Institute
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Study participating centre
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website

A description of this clinical trial will be available at https://www.ClinicalTrials.gov, as required by US law. The information will be also available in a similar European website, https://www.clinicaltrialsregister.eu and the public website ISRCTN registry, https://www.isrctn.com/, as required by UK law. These websites will include a summary of the results but will not include information that can identify a participant. These websites are available at any time. Should a participant wish to receive a copy of the results of this study once complete, they can request it from study doctor or nurse.

Intention to publish date
30/06/2029

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date