RNA Disruption Assay (RDA)-Breast Cancer Response Evaluation for Individualized Therapy
BREVITY (BREVITY)

ClinicalTrials.gov Identifier: NCT03524430

Recruitment Status: Recruiting
First Posted: May 14, 2018
Last Update Posted: May 14, 2018

See Contacts and Locations

Sponsor:
Rna Diagnostics Inc.

Information provided by (Responsible Party):
Rna Diagnostics Inc.

Study Description

Brief Summary:
The current study (BREVITY) aims to provide validation results of RNA Disruption Assay (RDA) as a tumour response assessment tool that uses tumour core biopsies at ~2 weeks after the initiation of neoadjuvant chemotherapy.

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<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
<th>Phase</th>
</tr>
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<tbody>
<tr>
<td>Breast Neoplasm Female</td>
<td>Procedure: Core needle biopsy</td>
<td>Not Applicable</td>
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Study Design

Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 722 participants
Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Diagnostic
Official Title: RNA Disruption Assay (RDA)-Breast Cancer Response Evaluation for Individualized Therapy (BREVITY)

Actual Study Start Date: April 26, 2018
Estimated Primary Completion Date: April 26, 2025
Estimated Study Completion Date: October 26, 2025

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics: Breast cancer
MedlinePlus related topics: Biopsy Breast Cancer
U.S. FDA Resources

Arms and Interventions

<table>
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<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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</table>
| Experimental: Single Interventionsal Study Arm | Procedure: Core needle biopsy
There will be one biopsy collection time point if there is no change of drugs, and 2 collection time points if a change is made to a different chemotherapy drug as part of the planned standard of care (SoC) treatment.
2 core needle biopsy specimens will be taken at each biopsy collection time point for RDA analysis during chemotherapy.

1st core needle biopsy for RDA 2 specimens: Time Point: ~2 weeks after initiation of 1st cycle of chemotherapy; Timing by type of drug schedule 3-weekly: at 16 days +/- 2 days, Bi-weekly: at day of 2nd dose preferably before drug admin., Weekly: at day of 4th dose preferably before drug admin.

2nd core needle biopsy for RDA: Time Point: if chemotherapy is changed (as part of SoC), a second biopsy ~2 weeks after initiation of new drugs; Timing by type of drug schedule 3-weekly: at 16 days +/- 2 days, Bi-weekly: at day of 2nd dose preferably before drug admin., Weekly: at day of 4th dose preferably before drug admin. |

Outcome Measures

Primary Outcome Measures:
1. Pathological complete response (pCR) [Time Frame: At surgery after completion of neoadjuvant therapy]
   (ypT0,ypN0) / (ypTis,ypN0)

Secondary Outcome Measures:
1. Disease-free survival [Time Frame: 5 years of survival follow-up]
   Time between diagnosis and first event of progression or death
Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: Female
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Must be 18 years of age or older;
- Willing and able to provide informed consent to participate in the RDA study;
- Newly diagnosed clinical stage II or III breast cancer with complete surgical excision of the breast cancer after neoadjuvant therapy as the treatment goal;
- Tumour size at least 2 cm in one dimension by clinical or radiographic exam (WHO criteria);
- Must have histological confirmation of invasive breast cancer of any subtype or grade;
- Patient is scheduled for neoadjuvant chemotherapy +/- antibodies by the multidisciplinary tumour board of the center;
- Patient willing to take a research core needle biopsy after the first cycle of chemotherapy - if the chemotherapy drugs will be changed as part of the planned treatment, patient agrees that a second biopsy will be taken after the first cycle of the new chemotherapy.

Exclusion Criteria:

- Patient who has had prior local (i.e. surgery or radiotherapy) or systemic (i.e. endocrine or cytotoxic) therapy for the current breast cancer;
- Concurrent treatment with other experimental drugs and/or participation in another interventional clinical trial;
- Stage I or IV breast cancer;
- Prior malignant disease except curatively treated basalioma of the skin or pTis of the cervix uteri;
- Concurrent pregnancy;
- Breast feeding woman;
- Concurrent medical, psychiatric or addictive disorders that may limit the ability to give informed consent or complete the trial;
- Reasons indicating risk of poor compliance with study procedures;
- Patient not able to consent.

Contacts and Locations

Information from the National Library of Medicine
To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03524430

Contacts
Contact: Sanaa Noubir, PhD  1-416-333-2931  snoubir@rnadiagnostics.com

Locations
Italy
ASST di Cremona U.O. Multidisciplinare di Patologia Mammaria e Ricerca Traslazionale
Cremona, Italy, 26100
Contact: Manuela Milani, MD

Sponsors and Collaborators
Rna Diagnostics Inc.

Investigators
Principal Investigator: Cornelia Liedtke, Prof. Dr med  Charité - Universitätsklinikum Berlin, CCM Klinikum für Gyr

More Information

Publications:


