A Study of Fluvestrant Combined With Oral Vinorelbine in Hormone Receptor-positive Advanced Breast Cancer

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03939871	RECRUITING	MAY 7, 2019	JUNE 23, 2020

STUDY DESCRIPTION

Brief Summary

This is a single-center phase II study designed to evaluated the efficacy and safety of fulvestrant in combination with oral vinorelbine in hormone receptor-positive advanced breast cancer

Condition or Disease: Hormone Receptor Positive Advanced Breast Cancer

Intervention/treatment: Drug: fluvestrant + oral vinorelbine

Phase: Phase 2

DETAILED DESCRIPTION

This is a single-group, single-center phase II trial. Patients with hormone-receptor-positive, Her2-negative recurrent or metastatic breast cancer who had not previously received any systemic antitumor therapy for advanced disease were treated with fulvestrant combined with oral vinorelbine as a first-line regimen. Key issues to be addressed in this study: to observe and evaluate the efficacy and safety of fulvestrant combined with oral vinorelbine in the treatment of hormone-receptor-positive and HER2-negative advanced breast cancer. Thirty patients are planned to be enrolled.

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 30 participants

Intervention Model : Single Group Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: Phase II Study of Fluvestrant Combined With Oral Vinorelbine in Hormone Receptor-positive Advanced Breast Cancer

Actual Study Start Date: December 2017

Estimated Primary Completion Date: December 2020

Estimated Study Completion Date: December 2020

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Single arm Fluvestrant in combination with oral Vinorelbine Fluvestrant: administered at a dose of 0.5g once im every 28 days. Vinorelbine: administered at a dose of 60mg/kg once a week for 3 weeks p.o. every 28 days.	Drug: fluvestrant + oral vinorelbine Eligible patients will be treated with the fluvestrant + oral vinorelbine regimen until the disease progresses or intolerable toxicity

OUTCOME MEASURES

Primary Outcome Measures: 1. Progression-free survival (PFS) [Time Frame: approximately 1.5 years]
PFS will be defined as the time from first dose of study drug until documentation of disease progression or death from any cause

Secondary Outcome Measures: 1. Objective response rate (ORR) [Time Frame: approximately 6 months]
The ORR will be calculated as the proportion of patients in the Efficacy Evaluable patient Set who achieve complete response (CR) and partial response (PR)
2. Incidence and Severity of adverse events [Time Frame: approximately 1.5 years]
hematologic toxicity□hepatotoxicity and so on

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 70 Years (Adult, Older Adult)

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Age between 18 and 75 year-old women; Pathologically or cytologically confirmed breast cancer; Hormone receptor-positive
- ECOG score: 0-1, expected survival time ≥ 3months;
- Recurrence after adjuvant therapy or metastatic breast cancer and chemotherapy naïve in the metastatic setting or had one prior regimen for metastatic breast cancer.
- Patients must have measurable disease according to RECIST criteria Version 1.1. Bone metastases lesions were excluded.
- The patients have adequate hematologic and organ function.
Exclusion Criteria:
- Patients with symptomatic brain metastases.
- Patients who are known or suspected to be allergic to the active ingredient or excipients of the investigational drug.
- Received ≥1 standard chemotherapy regimen (excluding endocrine therapy) for advanced breast cancer.
- Participation in other clinical trials within 4 weeks before enrollment.
- Severe cardiovascular disease, including history of congestive heart failure, acute myocardial infarction within 6 months before enrollment, transmural myocardial infarction measured by ECG, uncontrolled arrhythmia, angina requiring therapy, clinically significant valvular heart disease, uncontrolled hypertension.
- Severe or uncontrolled infection.
- Any factors that affect the oral administration and absorption of drugs (such as inability to swallow, gastrointestinal resection, chronic diarrhea and intestinal obstruction, etc.);
- Active malignancy in the past 5 years (other than carcinoma in situ of the cervix or basal cell carcinoma of the skin).
- Patients who are pregnant , breastfeeding ,or refuse to use adequate contraception during the course of participation.
- Need to concurrent other cancer therapy(other than palliative care for non-target lesions).
- Other ineligible conditions according to the researcher's judgment.

CONTACTS AND LOCATIONS

Contacts

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Locations

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Sponsors and Collaborators

Chinese Academy of Medical Sciences

Investigator

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MORE INFORMATION

Responsible Party :	Chinese Academy of Medical Sciences
ClinicalTrials.gov Identifier :	NCT03939871
Other Study ID Numbers :	NCC1564
First Posted :	May 7, 2019
Last Update Posted :	June 23, 2020
Last Verified :	June 2020
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Additional relevant MeSH terms :	*Breast Neoplasms*