

Re-treatment of pyrotinib in HER2-positive recurrent or metastatic breast cancer: a retrospective study

Submission date 25/03/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/04/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/04/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Breast cancer is the most common cancer in women globally, representing 11.7% of cases and a leading cause of cancer-related deaths (15.5%). It's classified into four types: luminal A, luminal B, HER-2-positive, and triple-negative. HER-2-positive breast cancer, comprising 15-20% of cases, is aggressive but treatable with targeted therapies like monoclonal antibodies and tyrosine kinase inhibitors (TKIs), offering advantages such as oral administration and reduced side effects. Pyrotinib, a Chinese-developed TKI, targets HER-2-positive breast cancer by blocking growth signals, proving effective, especially against brain metastases.

Resistance to treatment is a challenge, but recent evidence suggests potential effectiveness of re-treatment after a break. Investigating pyrotinib re-treatment in recurrent or metastatic HER2-positive breast cancer provides new treatment options, potentially improving survival and quality of life.

To assess this, researchers aim to collect real-world data on patient demographics, treatment history, pyrotinib dosing, supportive care, and clinical outcomes such as progression-free and overall survival. Understanding the safety profile of pyrotinib-based therapy is crucial for ensuring its safe use.

Who can participate?

Patients eligible for inclusion in the study are between the ages of 18 and 80 and have been diagnosed with recurrent or metastatic breast cancer confirmed as HER2-positive through pathology testing, with HER2 positivity defined by specific immunohistochemistry and in-situ hybridization criteria. Additionally, eligible patients must have undergone at least two lines of treatment containing pyrotinib for advanced disease and have a follow-up period of at least 2 months from the initiation of the pyrotinib-containing regimen. They must also exhibit a measurable lesion according to established criteria and possess adequate hematologic, hepatic, and renal functions.

What does the study involve?

The study is planned to include patients with HER2-positive recurrent or metastatic breast cancer. All patients included in the analysis have previously received a pyrotinib-containing regimen, with no restriction on the specific dosing regimen, and are fully guided by the physician's clinical choice, to assess the efficacy as well as the safety of re-treatment with a pyrotinib-containing regimen.

What are the possible benefits and risks of participating?

This is a retrospective study and patients may potentially benefit from the new treatment strategy of retreatment with pyrotinib.

In this study, pyrotinib treatment may trigger drug-related side effects, most commonly diarrhea. In addition to diarrhea, other possible side effects include neutropenia and anemia.

Where is the study run from?

The Second Xiangya Hospital of Central South University (China)

When is the study starting and how long is it expected to run for?

September 2023 to February 2025.

Who is funding the study?

This study was funded by the Innovation Platform and Talent Plan of Hunan Province (Grant No. 2023SK4019), the Science and Technology Innovation Program of Hunan Province (Grant No. 2021SK2026), the Clinical Medical Boot Technology Innovation Project of Hunan Province (Grant No. 2021SK53504), the Health and Family Planning Commission of Hunan Province (Grant No. 2022JJ70143), and the Clinical Research Special Fund of Wu Jieping Medical Foundation (Grant No. 320.6750.2022-19-29) (China)

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of re-treatment of pyrotinib in HER2-positive recurrent or metastatic breast cancer

Study objectives

Re-treatment with pyrotinib is effective in patients with HER2-positive recurrent or metastatic breast cancer.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 28/02/2024, Clinical Research Ethics Committee, The Second Xiangya Hospital, Central South University, China (No. 139, Renmin Middle Road, Furong District, Changsha, 410011, China; +86 731-85292476; xyf2gcp@126.com), ref: LYF20230190

Study design

Real-world multicenter retrospective cohort observational study

Primary study design

Observational

Study type(s)

Quality of life, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

Treatment for HER2-positive recurrent or metastatic breast cancer

Interventions

All patients included in the analysis have previously received a pyrotinib-containing regimen, with no restriction on the specific dosing regimen, and are fully guided by the physician's clinical choice, to assess the efficacy as well as the safety of re-treatment with a pyrotinib-containing regimen.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Pyrotinib Maleate Tablets

Primary outcome(s)

Progression-free survival (PFS) on the first pyrotinib treatment and PFS on re-treatment with pyrotinib) measured using patient records

Key secondary outcome(s)

Measured using patient records:

1. OS (overall survival)
2. ORR (objective response rate assessed by RECIST 1.1)
3. CBR (clinical benefit rate assessed by RECIST 1.1)

Completion date

27/02/2025

Eligibility

Key inclusion criteria

1. Patients aged ≥ 18 years and < 80 years.
2. Patients diagnosed with recurrent or metastatic breast cancer as HER2-positive by pathology testing (HER2-positive is defined as an immunohistochemistry (IHC) score of 3+ or 2+ for HER2 and a positive in-situ hybridization (ISH) test confirmed by a pathology laboratory).
3. Have received at least two lines of pyrotinib-containing regimens in advanced stages.
4. Have at least 2 months or more of follow-up data from the initiation of the pyrotinib-containing regimen to the point of data collection.
5. Presence of a measurable lesion as defined by the revised Response Evaluation Criteria in Solid Tumors 1.1 (RECIST 1.1).
6. Adequate hematologic, hepatic, and renal functions.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Key exclusion criteria

1. Pyrotinib medication use as neoadjuvant therapy.
2. Severe adverse side effects could not be controlled by dose reductions according to drug instructions.
3. Loss to follow-up for other unknown reasons.

Date of first enrolment

01/09/2023

Date of final enrolment

31/12/2023

Locations**Countries of recruitment**

China

Study participating centre**The Second Xiangya Hospital of Central South University**

139 Renmin Road, Changsha, Hunan Province

Changsha

China

410011

Study participating centre**Changde Third People's Hospital**

No.56, Gaoshan Road, Changde, Hunan, China

Changde

China

415000

Study participating centre**The First People's Hospital of Changde**

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Changde

China
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Study participating centre

Changde First Hospital of Traditional Chinese Medicine

No. 588, Binhu Road, Changde, Hunan, China

Changde

China

415000

Study participating centre

Chenzhou First People's Hospital

No. 102, Luo Jiajing, Chenzhou City, Hunan Province, China

Chenzhou

China

423001

Study participating centre

First Affiliated Hospital of Gannan Medical University

No. 23, Youth Road, Zhanggong District, Ganzhou City, Jiangxi Province, China

Ganzhou

China

341000

Study participating centre

Ganzhou People's Hospital

No. 17, Hongqi Avenue, Zhanggong District, Ganzhou City, Jiangxi Province, China

Ganzhou

China

341000

Study participating centre

The Second People's Hospital of Hunan Province

No. 427, Section 3, Furong Middle Road, Changsha, Hunan Province, China

Changsha

China

410007

Study participating centre

People's Hospital of Hunan Province

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China
410005

Study participating centre

Hunan Cancer Hospital

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China
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Study participating centre

General Hospital of Hunan Medical College

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China
410000

Study participating centre

Yiyang Kangya Hospital

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410008

Study participating centre

The First Hospital of Hunan University of Chinese Medicine

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Changsha
China
410007

Study participating centre

The Second People's Hospital of Huaihua

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China
418200

Study participating centre

The Fifth People's Hospital of Huaihua

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Huaihua

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418099

Study participating centre

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China

330029

Study participating centre

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417000

Study participating centre

The First Affiliated Hospital of Nanchang University

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Nanchang

China

330006

Study participating centre

Nanchang People's Hospital

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Nanchang

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330009

Study participating centre

The First Affiliated Hospital of University of South China

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China
421001

Study participating centre

Affiliated Nanhua Hospital, University of South China

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421002

Study participating centre

The Central Hospital of Shaoyang

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422000

Study participating centre

Shaoyang Hospital of Traditional Chinese Medicine

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422001

Study participating centre

The Second People's Hospital of Xiangtan City

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Xiangtan
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411100

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The First People's Hospital of Xiangtan City

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411100

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Xiangtan

China

411104

Study participating centre

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No.120 Heping Road, Xiangtan, Hunan, China

Xiangtan

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411100

Study participating centre

The First Affiliated Hospital of Jishou University

The Intersection of Qianzhou Shiji Road and Jianxin Road, Jishou City, Xiangxi Autonomous Prefecture, Hunan, China

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416000

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Xiangya Changde Hospital

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Changde

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415000

Study participating centre

Yichun People's Hospital

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Yichun

China

336000

Study participating centre

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Yiyang

China

413000

Study participating centre

The Third People's Hospital of Yongzhou

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Yongzhou

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425000

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Study participating centre

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335100

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Sponsor information**Organisation**

The Second Xiangya Hospital, Central South University

Funder(s)**Funder type**

Government

Funder Name

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Funder Name

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Funder Name

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Funder Name

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Funder Name

the Clinical Research Special Fund of Wu Jieping Medical Foundation (Grant No. 320.6750.2022-19-29)

Results and Publications**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