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

Submission date	Recruitment status	Prospectively registered
25/03/2024	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
03/04/2024	Completed	Results
Last Edited	Condition category	Individual participant data
02/04/2024	Cancer	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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Contact information

Type(s)

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Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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; xyf2qcp@126.com), ref: LYF20230190

Study design

Real-world multicenter retrospective cohort observational study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital, Medical and other records, Telephone

Study type(s)

Quality of life, Treatment, Safety, Efficacy

Participant information sheet

Not applicable (retrospective study)

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

Pharmaceutical study type(s)

Bioequivalence

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Pyrotinib Maleate Tablets

Primary outcome measure

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

Secondary outcome measures

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)

Overall study start date

01/09/2023

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

Age group

Mixed

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

360

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

No. 388, Renmin East Road, Changde, Hunan, China Changde China 415000

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

No. 61 Jiefang West Road, Changsha, Hunan, China Changsha China 410005

Study participating centre Hunan Cancer Hospital

No. 283 Tongzipo Road, Yuelu District, Changsha, China Changsha China 410013

Study participating centre

General Hospital of Hunan Medical College

No. 144, South Jinxi Road, Huaihua, Hunan Province, China Huaihua China 410000

Study participating centre Yiyang Kangya Hospital

No. 212, Zixi West Road, Heshan District, Yiyang City, Hunan, China Yiyang

Study participating centre

The First Hospital of Hunan University of Chinese Medicine

No. 95 Shaoshan Middle Road, Changsha, Hunan, China Changsha China 410007

Study participating centre

The Second People's Hospital of Huaihua

Wuxi Avenue, Hecheng District, Huaihua, Hunan, China Huaihua China 418200

Study participating centre

The Fifth People's Hospital of Huaihua

No. 615, Huaibei Road, Hecheng District, Huaihua, Hunan, China Huaihua China 418099

Study participating centre Jiangxi Cancer Hospital

No. 519, Beijing East Road, Nanchang, Jiangxi Province, China Nanchang China 330029

Study participating centre Loudi Central Hospital

No. 51 Changqing Middle Street, Loudi, Hunan, China Loudi China 417000

Study participating centre

The First Affiliated Hospital of Nanchang University

No. 17, Yongwai Zhengjie, Donghu District, Nanchang, Jiangxi Province, China Nanchang China 330006

Study participating centre Nanchang People's Hospital

No.2 Xiangshan South Road, Xihu District, Nanchang, Jiangxi, China Nanchang China 330009

Study participating centre

The First Affiliated Hospital of University of South China

No.69 Chuanshan Road, Hengyang, Hunan, China Hengyang China 421001

Study participating centre

Affiliated Nanhua Hospital, University of South China

No.336 South Dongfeng Road, Zhuhui District, Hengyang, Hunan, China Hengyang China 421002

Study participating centre The Central Hospital of Shaoyang

No. 36, Qianyuan Lane, Hongqi Road, Daxiang District, Shaoyang, Hunan, China Shaoyang China 422000

Study participating centre Shaoyang Hospital of Traditional Chinese Medicine

No. 631 Dongda Road, Shaoyang, Hunan, China Shaoyang China 422001

Study participating centre

The Second People's Hospital of Xiangtan City

No.38, Baimahu Road, Yuhu District, Xiangtan City, Hunan Province, China Xiangtan China 411100

Study participating centre

The First People's Hospital of Xiangtan City

No.100 Shuyuan Road, Yuetang District, Xiangtan, Hunan, China Xiangtan China 411100

Study participating centre

The Maternal and Child Health Care Hospital of Xiangtan City

No.295 Donghu Road, Xiangtan, Hunan, China Xiangtan China 411104

Study participating centre Xiangtan Central Hospital

No.120 Heping Road, Xiangtan, Hunan, China Xiangtan China 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 Xiangxi

China

416000

Study participating centre Xianqya Chanqde Hospital

No.1688, Yueliang Avenue, Langzhou North Road, Wuling District, Changde, Hunan, China

Changde China 415000

Study participating centre Yichun People's Hospital

No. 88, West Zhongshan Road, Yichun, Jiangxi, China Yichun China 336000

Study participating centre Yiyang Central Hospital

No. 118, North Kangfu Road, Yiyang, Hunan, China Yiyang China 413000

Study participating centre The Third People's Hospital of Yongzhou

No. 21, Yiyi Lane, Lengshuitan District, Yongzhou City, Hunan Province, China Yongzhou China 425000

Study participating centre The Central Hospital of Yongzhou

No. 151, West Xiaoshui Road, Lingling District, Yongzhou, Hunan, China Yongzhou China 425000

Study participating centre

Yongzhou Hospital of Traditional Chinese Medicine

No.1, Jiuyi Alley, Lengshuitan District, Yongzhou, Hunan, China Yongzhou China 425000

Study participating centre Yugan People's Hospital

No. 297, Century Avenue, Yuting Town, Yugan County, Shangrao City, Jiangxi Province, China Yugan China 335100

Study participating centre The Second People's Hospital of Yueyang

No.263 East Baling Road, Yueyang, Hunan, China Yueyang China 414000

Study participating centre The Fourth People's Hospital of Yueyang

Kaitai Road, Yunxi District, Yueyang City, Hunan Province, China Yueyang China 414000

Study participating centre Yueyang Central Hospital

No.39 Dongmaoling Road, Yueyang, Hunan, China Yueyang China 414000

Study participating centre Changsha Kexin Cancer Hospital

No. 292, Fenglin 3rd Road, Yuelu District, Changsha, Hunan, China Changsha China 410205

Study participating centre The Fourth Hospital of Changsha

No.70 Lushan Road, Yuelu District, Changsha, Hunan, China Changsha China 410006

Study participating centre Changsha Central Hospital

No. 161 Shaoshan South Road, Changsha, Hunan Province, China Changsha China 410004

Study participating centre

The Third Xiangya Hospital of Central South University

No.138 Tongzipo Road, Yuelu District, Changsha, Hunan, China China 410003

Study participating centre

Xiangya Hospital of Central South University

No.87 Xiangya Road, Changsha, Hunan, China Changsha China 410008

Study participating centre Zhuzhou Central Hospital

No. 116, Changjiang South Road, Tianyuan District, Zhuzhou City, Hunan Province, China Zhuzhou China 412007

Sponsor information

Organisation

The Second Xiangya Hospital, Central South University

Sponsor details

No. 139, Renmin Central Road Changsha China 410011 +86 731-85533525 kyb4080@163.com

Sponsor type

Hospital/treatment centre

Website

https://www.xyeyy.com/3042/3044/index.htm

Funder(s)

Funder type

Government

Funder Name

Innovation Platform and Talent Plan of Hunan Province (Grant No.2023SK4019)

Funder Name

the Science and Technology Innovation Program of Hunan Province (Grant No. 2021SK2026)

Funder Name

the Clinical Medical Boot Technology Innovation Project of Hunan Province (Grant No. 2021SK53504)

Funder Name

the Health and Family Planning Commission of Hunan Province (Grant No. 2022JJ70143)

Funder Name

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

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/06/2026

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