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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

Registration date
03/04/2024

Overall study status
Completed

Last Edited
02/04/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Type(s)

Public, Scientific

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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; xyf2gcp@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

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

Study participating centre
The Fifth People's Hospital of Huaihua
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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
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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
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Shaoyang
China
422001

Study participating centre
The Second People's Hospital of Xiangtan City
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Xiangtan
China
411100

Study participating centre
The First People’s Hospital of Xiangtan City
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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
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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
Xiangya Changde 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
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Yugan
China
335100

Study participating centre
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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
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Study participating centre
Changsha Kexin Cancer Hospital
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Changsha
China
410205

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410006

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Changsha
China
410004

Study participating centre
The Third Xiangya Hospital of Central South University
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Changsha
China
410003

Study participating centre
Xiangya Hospital of Central South University
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China
410008

Study participating centre
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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