A Phase 3, Randomized, Multi-center, Open-label Study of Trastuzumab Deruxtecan (T-DXd) versus Investigator*s Choice Chemotherapy in HER2-Low, Hormone Receptor Positive Breast Cancer Patients whose Disease has Progressed on Endocrine Therapy in the Metastatic Setting (DESTINY-Breast06)

Published: 23-06-2020
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This study has been transitioned to CTIS with ID 2024-516653-44-00 check the CTIS register for the current data. The primary purpose of the study is to determine the efficacy and safety of T-DXd compared with investigator*s choice single agent...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON52479

Source
ToetsingOnline

Brief title
DESTINY-Breast06

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breastcancer, Metastatic breastcancer

Research involving
Human

Sponsors and support

Primary sponsor: Astra Zeneca
Source(s) of monetary or material Support: AstraZeneca

Intervention

Keyword: Breast cancer, HER2-low, Metastatic disease, Trastuzumab Deruxtecan (T-DXd)

Outcome measures

Primary outcome

Assess the efficacy of trastuzumab deruxtecan compared to chemotherapy on

progression free survival (PFS) of the population

Secondary outcome

Assess the efficacy of trastuzumab deruxtecan compared to chemotherapy on

overall survival (OS) of the population

Assess the efficacy of trastuzumab deruxtecan compared to chemotherapy on

overall survival (OS) in the HER2 ICH>0<1 sub-group

Compare the 2 treatment arms in terms of ORR, DoRPFS2, TFST, TSST, HRQoL

Assess the safety of trastuzumab deruxtecan

Investigate the PK and immunogeneticity of trastuzumab deruxtecan

Study description

Background summary

The study is an open-label, multi-center, randomized study in HER2-low, HR+

breast cancer patients with disease progression on at least 2 lines of prior ET in the metastatic setting.Dit wordt vergeleken met chemotherapie (naar keuze van de onderzoeker).

Study objective

This study has been transitioned to CTIS with ID 2024-516653-44-00 check the CTIS register for the current data.

The primary purpose of the study is to determine the efficacy and safety of T-DXd compared with investigator*s choice single agent chemotherapy in the target population.

Study design

Approximately 850 patients (700 patients with HER2 IHC 1+/2+ expression and 150 patients with HER2 IHC>0 <1+ expression) will be randomized 1:1 to receive either trastuzumab deruxtecan or investigator*s choice chemotherapy (paclitaxel, nab-paclitaxel or capecitabine) until RECIST 1.1 defined progressive disease (PD),

Intervention

Arm A: treatment trastuzumab deruxtecan on day 1 of every 3-weekly cycle
ArmB: treatment with chemotherapy of investigator's choice (capecitabine, paclitaxel or nab-paclitacel)

Study burden and risks

Test subjects might visit the hospital more often en visits will take longer.
More procedures are performed compared to standard treatment. These procedures can cause complications and the study medication can cause side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Key Inclusion Criteria:
• Patients must be >=18 years of age.
• Pathologically documented breast cancer that:
1. is advanced or metastatic
2. has a history of HER2-low or negative expression by local test, defined as IHC 2+/ISH- or IHC 1+ (ISH- or untested) or HER2 IHC 0 (ISH- or untested)
3. has HER2-low or HER2 IHC >0 <1+ expression as determined by the central laboratory result established on a tissue sample taken in the metastatic disease setting
4. was never previously HER2-positive
5. is documented HR+ disease in the metastatic setting.
• No prior chemotherapy for advanced or metastatic breast cancer.
• Has adequate tumor samples for assessment of HER2 status
• Disease progression on endocrine therapy + CDK4/6 inhibitor within 6 months of starting first line treatment for metastatic disease and considered appropriate for chemotherapy as the next treatment by the investigator OR
• Disease progression on at least 2 previous lines of endocrine therapy with or without a targeted therapy (Progression of disease within 24 months on adjuvant ET is considered a line of therapy)
• Has protocol-defined adequate organ and bone marrow function.

Exclusion criteria

Key Exclusion Criteria:
• Ineligible for all options in the investigator*s choice chemotherapy arm
• Uncontrolled intercurrent illness or significant cardiovascular disease
• Active or prior documented ILD/pneumonitis or suspected ILD/pneumonitis that cannot be ruled out by imaging at screening
• Lung-specific intercurrent clinically significant illnesses
• Patients with spinal cord compression or clinically central nervous system metastasis.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-09-2021
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Enhertu
Generic name:	Trastuzumab-deruxtecan

Ethics review

Approved WMO Date:	23-06-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-02-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-02-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-09-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-11-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	01-04-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-11-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-07-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-12-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

(Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2024-516653-44-00
EudraCT	EUCTR2019-004493-26-NL
CCMO	NL73583.056.20