|  |  |
| --- | --- |
|  |  |

**Lay Protocol Synopsis**

|  |  |
| --- | --- |
| **Full study title:** | Multicentre, multi-country, prospective, observational, post authorisation safety study to describe the incidence of discontinuation due to diarrhoea within the first 3 months of a treatment with neratinib, in adult breast cancer patients treated in extended adjuvant in a real world setting: the NERLYFE study |
| **Lay language title:** | Observational study to describe treatment discontinuation due to diarrhea within the first 3 months of neratinib in adult breast cancer patients (NERLYFE) |
| **EU PAS Number:** | EUPAS41584 |

|  |
| --- |
| **What is the purpose of the trial?** |

Cancer is a disease that happens when some of the body's cells start to grow uncontrollably. Breast cancer is one of the most frequently diagnosed cancer. HER2+ breast cancer is a subtype of breast cancer which represents approximately 15% to 25% of breast cancer worldwide.

Nerlynx® is an oral agent containing the active substance neratinib. Nerlynx® has been approved firstly in United States of America in 2017, and in Europe in 2018. Nerlynx is used in people who have early stage breast cancer which:

* Is hormone receptor positive (HR-positive) and human epidermal growth factor receptor 2- positive (HER2) overexpressed/amplified (HER2 positive), and
* Has previously been treated with trastuzumab based therapy that ended less than one year ago.

With this treatment, people may have diarrhoea leading to treatment discontinuation. Therefore, before starting neratinib treatment patients received educational material (EM) containing instruction on how to prevent and manage diarrhea if it occurs. This study is a post-authorisation safety study (PASS). This study aimed to see how many people had diarrhoea leading to neratinib discontinuation within the first 3 months. The study aimed also to assess the usage and effectiveness of the anti-diarrhea measures.

|  |
| --- |
| **What are the objectives of the trial?** |

The primary objective was to describe the incidence of discontinuation due to diarrhoea within the first 3 months of treatment with neratinib.

The key secondary objectives were:

* To characterise diarrhoea patterns
* To describe neratinib treatment maintenance
* To assess the accessibility, understanding, adherence of the educational material
* To describe the impact of the treatment on the quality of life

|  |
| --- |
| How is the trial conducted? |

The study was an observational, PASS, real-world study. A PASS study is a safety study that is done after a drug has been authorized for use. The aim is to obtain further information on the safety of a drug used as approved by the Health Authorities. An observational study looks at how things work in everyday life. Therefore, inclusion and exclusion criteria are less strict compared to clinical interventional trials; as the aim is to reflect the clinical practice of a drug already approved and available in a given indication.

This study was done in people for which the physicians decided to treat them with neratinib. The people should have access to documents with information on neratinib (educational materials). The main objective of the study was to collect information on diarrhoea in the first 3 months with neratinib treatment.

This study included:

* A first phase of 3 months of treatment with neratinib
* The second phase up to 12 months of treatment with neratinib.

|  |
| --- |
| Who can take part in the trial? |

The study took place in Europe.

The following people could participate in the study:

* Adult people
* With early stage HER2+ overexpressed/amplified breast cancer
* Who received neratinib as per the Summary of Product Characteristics (SmPC)
* Who received educational material
* Who agreed to participate in the study

|  |
| --- |
| **What are the trial treatments and how are they administered?** |

People received neratinib prescribed by their physician. As per inclusion criteria neratinib should be used as indicated in the Summaries of product characteristics (SmPC). The SmPC is a document approved by the Health authorities. The SmPC is used as basis of information for healthcare professionals on how to use the medicine safely and effectively. The dose received was the one effectively received during the study.

|  |
| --- |
| **Ethical considerations** |

This study was conducted according to ethical considerations and followed the rules for conducting such study in each participating country. The study did not start before it was approved as per local regulation. People provided their consent to participate in.

|  |
| --- |
| **What are the possible benefits and risks in taking part in the trial?** |

People were prescribed with neratinib by their physician, according to the usual routine practice. People received information on the study as well as educational material. Participation in this study meant that people had questionnaires to fulfil in.

There were no risks or discomforts not direct benefit expected due to the participation in this study. However, this study was expected to increase the knowledge of breast cancer and neratinib treatment.