Lay Protocol Synopsis

Lay language title:	Observational study: effect of dermatological toxicities on quality of life in patients treated for early breast cancer
Full study title:	Impact of dermatological toxicities on quality of life in patients with early breast cancer exposed to adjuvant endocrine therapy: a real-world cross-sectional study BCARE (Breast Cancer Adjuvant Real-world Evaluation of Dermatological adverse events)
Registry Number:	NCT06690489

1 What is the purpose of the study?

Cancer is a disease that happens when some of the body's cells start to grow uncontrollably. Patients with breast cancer treated with anti-cancer treatment may have dermatological toxicities. These toxicities include mostly skin inflammation, hair changes, or facial flushing. These effects could be associated with negative effects on the quality of life. Therefore, it is important to reduce these effects to improve the quality of life. This will help patients to continue to take their anti-cancer treatment.

This study is an observational and transversal study. An observational study looks at how things work in everyday life. A transversal study means that data have been collected the day of the inclusion of people, and that no specific follow-up is planned in this study. This means that there are no additional visits, procedure, treatments or additional examinations compared to your usual medical care.

The aim of this study is to describe in patients with early breast cancer treated with adjuvant endocrine therapy*:

- The dermatological toxicities, and,
- Their impact on quality of life.

* Adjuvant endocrine therapy is a treatment given to patients, usually after first treatments received like surgery, to help prevent the return of hormone-sensitive cancers. It works by blocking or lowering the amount of hormones, such as estrogen, in the body. This can help to decrease or stop the growth of cancer cells linked to these hormones.

2 What are the objectives of the study?

The primary objective is to describe the quality of life related to dermatological toxicities. This will be evaluated using a Dermatology Life Quality Index (DLQI) questionnaire. The questionnaire will be completed by people who participate in the study.

The secondary objectives are to describe:

- The dermatological quality using questionnaires for skin and hair
- To dermatological toxicities present at entry in the study
- The demographics and clinical characteristics.

3 How is the study conducted?

This study is conducted in Europe (France, Greece, Italy, Spain).

To describe dermatological toxicities, people should complete the day of their inclusion at maximum 4 questionnaires: un sur la qualité de vie, un sur les cheveux, et deux sur la peau.

This study is a real-life study. Therefore, this study is done in people followed by their physician according to the local clinical practice. There is no follow-up planned, nor safety data collected.

4 Who can take part in the study?

The following people could participate in the study:

- Women aged ≥ 18 years
- With early breast cancer
- Still being treated with adjuvant endocrine monotherapy, initiated from 2 to 3 years before the inclusion in the study.
- Who consented to participate in the study.

5 What are the study treatments and how are they administered?

There is no specific treatment linked to the study. The study has started after people had initiated their anti-cancer treatment. This anti-cancer treatment had been prescribed by their physician. This treatment was in accordance with the planned care.

6 Ethical considerations

This study is 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.

7 What are the possible benefits and risks in taking part in the study?

This study does not require starting new treatments nor changes in the diagnostic and treatment follow-up by your doctor. You will only need to complete four questionnaires. There are no health risks associated with your participation in this study.
You should not expect any personal benefit from participating in this study. However, your participation will help the Sponsor to better understand the quality of life of people with breast cancer, and treated with adjuvant endocrine therapies. We hope the information learned from this study will benefit others in the future.