

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: ARIMIDEX
ACTIVE INGREDIENT: anastrozole

Study No: NCT01081509
NIS-OHU-ARI-2010/1

Developmental Phase: Non-Interventional

Study Completion Date: 16 October 2011

Date of Report: 6 August 2012

OBJECTIVES:

Survey and follow-up of the treatment adherence and medication habits of early breast cancer patients on adjuvant hormonal therapy with the aromatase inhibitor anastrozole

METHODS:

Patient population

Early breast cancer diagnosed patients on adjuvant hormonal therapy with the aromatase inhibitor anastrozole.

Design

Prospective, multicenter, observational cohort study.

Study Drug

All patients in this study were treated with aromatase inhibitor anastrozole in accordance with local standard clinical practice in Hungary.

Statistical analysis

Descriptive statistical methods were used for data analysis. Statistical analyses were performed with SAS 9.1.3 SP4.

RESULTS:

At the starting rounds in 70 centres altogether 1073 patients were involved in the controls every quarter year and at the final round 1058 patients turned up. This resulted a 98.6% of the patients. The average age was 50.28 years.

During the rounds the physicians filled in the EORTC PATSAT 32 questionnaire, which analysed in 11 points the main elements of keeping contact with patients in 1-5 differing categories (from unsatisfactory to excellent). The time limit for a round was found the worst parameter by the physicians 18% out of the patients only received listing 3.

The feedback for the most important question concerning adherence of the patients was very positive. Only two patients gave up taking the aromatase inhibitor (AI) and in four cases changed to another medicine. The habit of taking medicine did not specifically change with the increasing number of rounds due to the fact that 98% of the patients knew the reason of taking the medicine, was prescribed by the similar physician and they were aware of the fact that by giving up medicine the risk of cancer relapse would increase.

At the starting round the proportion of those patients taking medicine regularly was 96% which grew to 98.3% at the final round. Another important result was that while only 85% of the patients did not stop taking medicine at the starting round when feeling ill by the final round this number increased to 96%. Thus the number of patients giving up taking medicine dropped from 15% to 4%, which can be attributed to the given appropriate information.

Discussion:

Adherence in the treatment of chronic illnesses is one of the most important factor of efficiency. In the course of clinical examinations on patients with breast tumour receiving adjuvant treatment following a longer time period(>4 years)it was generally experienced that 23-28% of patients receiving hormone therapy (tamoxifen or AI) terminated the treatment before time.

The surprising good results of the Ariadne examination is made up of several factors. The regular rounds,the tighter physician and patient contact as well as the questions, the follow-ups, the answers and explanations of the questionnaire made the possibility of a personal assist. The appropriate communication between patient and physician helped in understanding the reasons and the methods of the treatment. The patients were informed about why the given treatment was useful and in this way their faith in the treatment was consolidated.