A Clinical Trial of a New Combination of Two Cancer Drugs for Breast Cancer

Thank you for participating in this study.

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and help them discover new medical treatments.

The sponsor (researcher) of this study thinks it is important for you to know the results. We hope it helps you understand and feel proud of your key role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

Here we describe the results of this study.

This summary was completed in March 2016. Newer information since this summary was written may now exist. This summary includes only results from one single study. Other studies may find different results.

This study tested a new combination of treatments for people with advanced breast cancer.

Why the study was done

Breast cancer takes the lives of as many as 40,000 women each year. Researchers are looking for medical treatments to help women with advanced breast cancer live longer and better lives.

This study was done to find out for how long the combination of the drugs [DRUG A] and [DRUG B] could stop a particular type of breast cancer from growing. If a breast cancer has a protein called HER2, it is called “HER2-positive.” Women in this study did not have cancers that had the HER-2 protein, and are called “HER-2 negative.” This was important because different medical treatments would be used if the tumor did or did not have this protein. The cancer had been treated in an early stage but it came back.

Researchers also wanted to know if tumors would get smaller for any of the patients, and how many of the patients would survive for at least one year. All of the patients in this trial were expected to survive for at least 6 months. In addition, it was important to find out what side effects the two drugs had.
Study information

This was an “open-label study.” That means everyone—patients and study staff—knew which drugs the patients were getting. All of the patients took the same two drugs: [DRUG A] plus [DRUG B].

This study included:

- Study group: From 19 locations across Europe, 63 women 18 years or older with advanced breast cancer were included. On average, patients age was 55 years.
- Treatment: [DRUG A] is a drug used to treat breast cancer that has spread to other parts of the body and has not gotten better with other drugs. [DRUG B] is a drug used to slow the growth of several types of cancer. The same combination of [DRUG A] and [DRUG B] had previously been tested by patients with advanced cancer of the pancreas (a part of the digestive system).

This study started in March 2006 and finished in January 2009.

This study may have finished before other studies that also study this end. When all the studies are complete, the researchers will look at the results across the studies.

How the study worked

*Patients got the study drugs every 3 weeks.* At each study site, staff gave each drug as a liquid, through a needle inserted in a vein (an “IV infusion”). Patients got [DRUG A] first. This took about 20 minutes. Then [DRUG B] was given. This took about 40 minutes the first time. In later visits, study staff tried giving [DRUG B] over a shorter period of time, and they checked that this was safe.

*Study staff checked patient’s health at each* study visit, including blood pressure, temperature, heart rate, body weight, and how fast people were breathing. Blood tests and other lab work were also done. If tumors could be felt, they were measured every 4 weeks. Every 8 weeks, tumor size was measured with medical imaging equipment.

*Patients stopped getting the study drugs if* the cancer started to grow, or if different medical treatment was needed for other reasons. If the cancer grew, that meant it was getting worse and the drugs were no longer working. Patients also stopped getting the study drugs if the side effects were too bad, if their doctor thought stopping was in their best interest, or if they wanted to stop for any reason.

*Patients kept going for follow-up visits* after they stopped getting the study drugs. A final visit occurred 15 days after the last treatment. Again, study staff checked for cancer growth and side effects. After that, patients were seen every three months until the study closed.
Side effects

A side effect is any medical problem from a drug or treatment. A lot of research is needed to know whether a medical problem is caused by a drug or treatment. So, when new drugs are being studied, researchers keep track of all medical problems that patients have. These medical problems are called “adverse events,” and may or may not be caused by the study drugs. A list of adverse events is an important part of the study results. This section tells about the adverse events found in this study.

60 of 63 patients had less-serious adverse events. These adverse events were not life-threatening. The table below shows the most common of the fifty types of less-serious adverse events found in this study.

<table>
<thead>
<tr>
<th>Most common less-serious adverse events</th>
<th>Number of patients (out of 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>36</td>
</tr>
<tr>
<td>Tiredness</td>
<td>35</td>
</tr>
<tr>
<td>Constipation</td>
<td>20</td>
</tr>
<tr>
<td>Anemia</td>
<td>18</td>
</tr>
<tr>
<td>Reduced appetite</td>
<td>17</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>17</td>
</tr>
<tr>
<td>Vomiting</td>
<td>16</td>
</tr>
<tr>
<td>Low neutrophil (type of white blood cell)</td>
<td>16</td>
</tr>
<tr>
<td>Protein in urine</td>
<td>14</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>12</td>
</tr>
<tr>
<td>Back pain</td>
<td>10</td>
</tr>
<tr>
<td>Headache</td>
<td>9</td>
</tr>
</tbody>
</table>

24 of 63 patients had adverse events considered serious, and 39 of 63 did not. An adverse event is considered serious if it is life-threatening, if it puts you in the hospital or keeps you there for a long time, if it causes a birth defect, or if it could cause long-term disability.

<table>
<thead>
<tr>
<th>Serious adverse events</th>
<th>Number of patients (out of 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute kidney failure</td>
<td>2</td>
</tr>
<tr>
<td>Anemia</td>
<td>2</td>
</tr>
</tbody>
</table>
Congestive heart failure                        2
Blood clot in the lungs                         1
Blood infection                                 1
Fluid retention                                 1
HUS (syndrome with destruction of red blood cells and kidney injury) 1
Low neutrophil (type of white blood cell) count, with fever 1
Low platelet count                              1
Low white blood cell count                      1
RPLS (syndrome with headache, confusion, seizures and vision loss) 1
Skin infection                                  1

**Summary of results**

These results are for women over 18 years old who have HER2-negative advanced breast cancer and took the study drugs [DRUG A] and [DRUG B].

Results are limited to the particular people studied here and cannot be assumed to be true for everybody. Not all participants in each part of the study had the same results.

The study found that:

On the whole, patients’ cancer stopped growing for almost 5 months. But the results were different for each patient.

Measured tumors got at least 30% smaller in 20% of patients. In the other 80% of patients, tumors either grew larger, stayed the same size, or got smaller but by less than 30%.
Two thirds of the patients (66%) survived their breast cancer for at least one year after starting the study drugs. One third of the patients (34%) passed away within one year.

66% of patients survived one year
34% of patients did not survive one year

Final comments

This research may help future patients and families by helping us understand more about breast cancer treatments. Findings from this study will be used to inform future research.

This study is officially known as: xxxxxxxxxxxx
ClinicalTrials.gov identifier: NCTxxxxxxxx.
At that web page, you will find a link to the full scientific report.

You can also find more details about this study at:

- xxxxxxxx

For more information about the HER2-positive breast cancer:

- http://www.breastcancer.org/symptoms/diagnosis/her2
- http://www.healthline.com/health/breast-cancer/her2-positive-survival-rates-statistics#Prognosis8

For general information about research studies, go to

This research was important. If you have questions about the results, please speak with the doctor or staff at your study site.

Thanks again for being part of this study. We do research to try to find the best ways to help patients, and you helped us to do that.