

COMET PATIENT RECRUITMENT MATERIALS

COMET Study Patient Brochure

COMET Study (AFT-25): A Clinical Trial for Low Risk Ductal Carcinoma in Situ (DCIS)

What is COMET?

The *Comparison of Operative to Monitoring and Endocrine Therapy for Low Risk DCIS* (COMET) study is a clinical trial that looks at different treatment choices for ductal carcinoma in situ (also called DCIS).

DCIS is a non-invasive breast condition where cells that do not appear to be normal are found in the milk ducts. These cells are often harmless and may not need treatment.

The study will compare two groups of women who are 40 years of age or older and have been diagnosed with low-risk DCIS.

This is the first national study that will find out if low-risk DCIS can be safely watched with close monitoring. This may help future women to avoid breast surgery for low-risk DCIS.

We plan to enroll about 1200 patients at 100 sites across the US.

Women may be asked to join this study if the doctor thinks they are eligible. Participants will be randomized into one of two treatment groups by chance. This is done because no one knows if one treatment is better than another. The two treatment groups are:

- Breast surgery (with the option of radiation and/or endocrine (hormone-blocking) therapy).
- Active surveillance (sometimes called “close monitoring” or “watchful waiting”) with the option of endocrine (hormone-blocking) therapy.

Active surveillance means a condition is closely watched with more follow-up exams and tests such as mammograms. If the condition of the patient changes in some way, then they may be safely treated with breast surgery and sometimes radiation therapy.

Why is the COMET study being done?

Currently, **all** types of DCIS are treated with breast surgery and often radiation therapy.

The COMET study will help researchers and doctors learn more about low-risk DCIS by closely watching some women who do not have surgery.

Our goal is to find out if some women can safely avoid surgery and radiation and their possible side effects which include pain, infection, scarring, and other changes to the breasts. However, active surveillance may not have equal or better outcomes than standard care treatments and there is a chance that your DCIS may change over time.

Who may be eligible to join the COMET study?

- Women with low-risk DCIS
- Women who are 40 years of age or older
- Women who do not have a personal history of breast cancer or prior treatment of DCIS.

Why would women join the COMET study?

- Low-risk DCIS is not a threat to a woman's life.
- Some women may want to avoid or delay surgery while being closely watched by their doctors.
- Close monitoring of low-risk DCIS may result in the same excellent outcomes as the standard treatments of surgery and radiation, but with fewer physical and/or emotional side effects that many women experience with standard treatment.
- Participation in this trial is valuable and appreciated. This study helps patients, researchers and doctors learn more about DCIS.
- Joining this trial is a chance for DCIS patients to improve the lives of future generations of women diagnosed with DCIS.

To learn more about this study or see if you may be eligible, talk to your doctor or go to:

www.DCISoptions.org

This work is supported through a Patient-Centered Outcomes Research Institute (PCORI) Award (PCS-1505-30497).

Welcome to the DCIS decision support tool

DCIS stands for ductal carcinoma in situ. It is a condition in which abnormal cells are found in the lining of the breast duct. In most cases of DCIS, these abnormal cells have not spread outside the duct to other tissues of the breast. Current research suggests that some types of DCIS may never become harmful to health within a woman's natural life time.

The purpose of this **interactive decision support tool** is to help you and your doctor make a personalized treatment decision that is right for you. In particular, we will try to help you answer the following questions:

- What are my options for treatment?
- How can my choice of treatment change the chance of having a future DCIS **or** invasive breast cancer diagnosis in the next 10 years?
- How can my choice of treatment impact the chance I will be alive in 10 years? Note that of 100 women treated for DCIS, the chance of dying from breast cancer is very small. Indeed, doctors are testing strategies for less treatment or sometimes no treatment for selected DCIS patients

This decision support tool is designed to be used in consultation with a doctor.

What is uncertainty?

Uncertainty is when outcomes are not known. For example, it is uncertain if some types of DCIS will be associated with a future cancer.

What are risk estimates?

Risk estimates approximate how likely it is that a future condition will happen. For example, recurrence risk estimates give an indication of how likely it is that a future DCIS or cancer will be experienced in the breast within a certain time after treatment.

All risk estimates given in this tool are absolute risks.

TO LEARN MORE ABOUT TYPES OF RISK AND HOW RISK ESTIMATES ARE DETERMINED, CLICK [HERE](#)

TO LEARN MORE ABOUT RISK AND DCIS DECISIONS CLICK [HERE](#)

Why use a decision support tool?

A decision support tool may be beneficial for patients and caregivers who are making decisions that come with uncertainty. It can help them understand each treatment choice and what may happen with each choice.

What information do I need to use the decision support tool?

This decision support tool is designed to provide estimates for your chances of having certain health conditions at **10 years**. If you have information that your DCIS is low risk (low or intermediate grade), then you can click the “low-risk” box. If you have information that your DCIS is high risk, then you can click the “high-risk” box. If you don’t know, you can click the “don’t know” box and get an average of the estimated numbers.

Patients at low risk may also be eligible for the COMET study which may require no surgery for DCIS. However, the risk estimates described in this decision support tool are only for those who have surgery. To learn more about having no surgery for DCIS or doing active surveillance click [here](#).

No surgery for DCIS and doing active surveillance

Some women with low-risk DCIS are thought to be unlikely to have a future invasive breast cancer. These women could be followed closely instead in a type of management called “active surveillance.” Surgery would only be performed if invasive cancer is detected at a later date. Active surveillance does not mean patients are “doing nothing,” it requires that the patient and her healthcare closely monitor the DCIS. This management strategy is based on results from limited studies showing that surgery for low-risk DCIS may not affect a woman’s survival. There are ongoing studies to evaluate active surveillance further. To learn more about one available study, please click [here](#) [COMET study website link].

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If you are interested in learning more about active surveillance for some women with low-risk DCIS, please refer to links to the information below [add links].

Note: This decision support tool is designed to be used in consultation with a doctor.

Things to keep in mind while using the tool

Use the decision support tool menu to navigate to the absolute risks for each treatment type you are interested in.

Risk estimates are one piece of information that can help you make a decision. You may also want to consider what else is important to you such as short and long-term side effects, family, time commitments, financial concerns, work responsibilities and quality of life.

There is no wrong or right answer when it comes to your treatment decision. It is important to choose a treatment that is right for you based on your circumstances and what you value most in your health care.

Tell us about yourself

How old are you?

What grade DCIS do you have?

- 1) Low or intermediate grade
- 2) High grade
- 3) Don't know

I have read and accept the Terms and Conditions.

Terms and conditions

The decision support tool on this website is for patients diagnosed with ductal carcinoma in situ (DCIS) who are able to enter their patient and laboratory test data and work with their physician to interpret the decision support tool's output.

This decision support tool is not intended for patient use alone because some women may not be a candidate for certain options presented in the

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tool. The patient's physician will be able to tell her which options she is eligible for. If you are a patient and wish to use this decision support tool to obtain results for yourself, please bring the Web address of this site (URL goes here) to your physician so that they may generate and review the results with you.

This website does not provide specific medical advice. If you have concerns about your health, please consult a health care professional.

Every effort has been made to ensure that the information on this website is accurate, but it may not reflect the current state of medical research, which is continually changing. This website is not responsible for any loss or damage resulting from any inaccuracy in its information.

If you have questions about the decision support tool, please [Contact us](#).

Available treatments

This page provides information about the various treatments available to women with DCIS. Your doctors will discuss the risks and benefits of these treatments in more detail.

[Lumpectomy](#)

A **lumpectomy** (also called breast conserving surgery or partial mastectomy), is a surgery that removes the DCIS tissue from your breast. Most women can go back to regular activities two weeks after surgery. Possible side effects include: loss of sensation, scarring, breasts that don't match in size or shape, and pain or discomfort that can be long-term.

[Lumpectomy plus radiation therapy](#)

Radiation therapy is typically started 2-6 weeks after lumpectomy. High-energy radiation is used to kill cancer cells. To receive radiation therapy, you will visit the clinic every weekday for 3-6 weeks. At each visit, you are in the treatment room for 10-20 minutes. Possible side effects of radiation therapy include: fatigue, skin redness or irritation. Rare long-term sided effects may include secondary cancers and heart or lung problems.

[Lumpectomy plus endocrine therapy](#)

After a lumpectomy (see above), if your DCIS is estrogen receptor positive (ER+), you may consider taking an endocrine-blocking pill daily to block hormones for 5 to 10 years. Possible side effects of endocrine-blocking therapy include fatigue, hot flashes, vaginal dryness, low libido, mood swings, body aches and nausea. Endocrine-blocking therapy is not an option for ER-negative DCIS.

[Lumpectomy plus radiation and endocrine therapy](#)

The combination of all the treatments described above.

[Mastectomy with or without reconstruction](#)

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A mastectomy is a surgery to remove the entire breast. If you are considering this option, your doctor may also suggest reconstruction surgery. Reconstruction surgeries are done to rebuild evenness between the two breasts by replacing skin, breast tissue and/or the removed nipple. Breast reconstruction can be done with an implant material or by moving fat or muscle from another part of your body. Side effects of mastectomy and reconstruction can include physical side effects (bruising, bleeding, pain, loss of feeling); there may also be emotional and psychological side effects, and financial costs, all of which could have an impact on your daily life.

[Bilateral mastectomy with or without reconstruction](#)

A bilateral mastectomy is a surgery to remove both breasts entirely. If you are considering this option, your doctor may also suggest reconstruction surgery. Reconstruction surgeries are done to rebuild the two breasts by replacing skin, breast tissue and/or the removed nipple. Breast reconstruction can be done with an implant material or by moving fat or muscle from another part of your body. Side effects of mastectomy and reconstruction can include physical side effects (bruising, bleeding, pain, loss of feeling); there may also be emotional and psychological side effects, and financial costs, all of which could have an impact on your daily life.

Active Surveillance

This is a treatment which involves no surgery for DCIS. Instead, you will have regular follow-up screening to monitor for any changes. Additional therapies including surgery will be reviewed and discussed if changes occur.

A clinical trial is underway to gather data about this option. You may be eligible for this trial comparing the outcomes of active surveillance to surgery depending on your age and DCIS characteristics. See the COMET tab ([here](#)) for more information. Active surveillance is currently not being offered as standard of care. To learn more about having no surgery for DCIS or doing active surveillance click [here](#).

Learn about treatment(s)

On this page you can select the treatment(s) for DCIS that you may be interested in. Treatments that involve endocrine therapy may not be available to you depending on your Estrogen Receptor (ER) status. If you know your ER status, please enter it below. If not, that's fine, just select the treatment(s) that you would like to learn more about.

What treatment(s) are you interested in?

- Lumpectomy only
- Lumpectomy + Radiation
- Lumpectomy + Endocrine therapy
- Lumpectomy + Radiation + Endocrine therapy
- Mastectomy (with or without reconstruction)
- Bilateral Mastectomy (with or without reconstruction)

Once you have selected the treatment(s) that you are interested in, touch next to continue.

Health risk estimates (absolute risk)

Based on the information you provided about yourself, we have estimated the effect on your health for each treatment option you are considering. The health risk estimates will be shown on the following pages:

1. The chance of a future DCIS or the chance of developing invasive breast cancer in the same breast in the next 10 years. Invasive breast cancer occurs when cancer cells from inside the milk ducts or lobules break out into nearby breast tissue.
2. The chance of dying from causes **other than breast cancer** in the next 10 years.
3. The chance of dying from breast cancer in the next 10 years.

When you are ready, please touch next to continue.

Understanding risk associated with DCIS

Lumpectomy only

Within 10 years, out of 100 women diagnosed with DCIS and treated with Lumpectomy only

82

women will not have a future DCIS or develop invasive cancer in the same breast

6

women will develop invasive cancer in the same breast

7

women will have a a future DCIS in the same breast

4

women will die from causes **other than breast cancer**

1

woman will die from breast cancer

Understanding risk associated with DCIS

Lumpectomy + Radiation + Endocrine therapy

Within **10 years**, out of 100 women diagnosed with DCIS and treated with Lumpectomy + Radiation + Endocrine therapy

71

women will not have a future DCIS or develop invasive cancer in the same breast

10

women may or may not have a future DCIS or develop invasive cancer in the same breast

11

women will have a future DCIS or develop invasive cancer in the same breast

7

women will die from causes **other than breast cancer**

1

woman will die from breast cancer

Which treatment option is best for me?

When choosing which treatment option is best for you, you may want to consider the following questions:

1. What are my treatment goals?
2. What are the issues that are most important to me?

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3. How important is keeping my breast to me?
4. How would a mastectomy affect the way I feel?
5. How would the radiation therapy treatment schedule affect my daily routine? (Reminder: To receive radiation therapy, you must go into clinic every weekday for 3-6 weeks.)
6. What is my estrogen receptor status, and how does it affect my treatment options?
7. Am I willing to take a hormone-blocking pill every day?
8. How do I feel about the possibility that I could have a future DCIS or develop invasive cancer?
9. If I think I have low-risk DCIS, I may be eligible for a trial. Researchers are conducting trials to gather data on a treatment which may involve no up-front surgery for DCIS. You may be eligible for this trial comparing the outcomes of active surveillance to surgery depending on your age and DCIS characteristics. To learn more about having no surgery for DCIS or doing active surveillance click [here](#).

When you are ready, please touch next to continue.

Should I take part in a clinical trial?

As you make your treatment decisions, you may want to think about joining a clinical trial. Clinical trials are studies of new treatments and the benefits and risks are often not yet fully understood, but they offer the opportunity to receive the newest treatments while being very closely watched. Most of the standard treatments were first studied in clinical trials.

By looking closely at all options, including clinical trials, you are taking an active role in a decision that impacts your life. Participating in a clinical trial is completely voluntary.

Where can I find a list of clinical trials for DCIS?

To find a list of clinical trials for DCIS, you can:

1. Visit www.BreastCancerTrials.org and search for DCIS
2. Visit www.ClinicalTrials.gov and search for DCIS
3. Visit www.cancer.gov/clinicaltrials/ and search for DCIS
4. Call [The National Cancer Institute Information Service](http://TheNationalCancerInstituteInformationService) at: **1-800-4-**

CANCER

When you are ready, please touch next to continue.

Questions for my care team

Examples of questions to ask my care team at the next visit:

1. Can you tell me about any long-term effects of any of the treatments?
2. If I chose endocrine therapy, which is best for me and what are the side effects?
3. How long will I need to be on endocrine therapy?
4. Can I have radiation at my local treatment center or do I have to go to a different location?
5. What do we know about the side effects of each treatment?
6. Should I join a clinical trial?
7. Other questions specific to my circumstances (consider other health conditions, family history, financial considerations or work obligations).
8. Is there information about outcomes beyond 10 years?

When you are ready, please touch next to continue.

Next steps

There is no wrong or right answer when it comes to treatment, it is important to choose a treatment that is right for you.

When you are ready, please touch next to continue.

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Active surveillance

Active surveillance involves frequently monitoring a patient's condition. Treatment is not undertaken unless test results show that the condition has gotten worse. It aims to protect quality of life by delaying surgery unless it becomes necessary.

Lumpectomy/Breast-Conserving Surgery

Breast-conserving surgery is less radical surgery than mastectomy (a lumpectomy is an example of breast-conserving surgery). Breast-conserving surgery only removes part of the breast tissue during surgery, as opposed to the entire breast. A small amount of healthy, normal tissue around the DCIS is also removed. This is to make sure that this area is clear of any abnormal cells. This is called a clear margin.

Endocrine (hormone-blocking) therapy

Endocrine (hormone-blocking) therapy is typically used for DCIS that responds to treatment that blocks hormones. Medication to control hormone levels may lower future risk of either a future DCIS or invasive breast cancer. However, benefits of these medications should be weighed against potential side effects.

Radiation therapy

Radiation therapy is a treatment where the breast is treated with radiation beams to reduce the chance of future DCIS or breast cancer. Radiation may not be necessary for all women with DCIS, particularly those patients with low-risk DCIS. It may provide peace of mind by lowering the chance of a future breast condition. But there are side effects and it can only be done once on each breast; this is important in case breast cancer develops in the future.

Mastectomy

A mastectomy is surgery which removes the entire breast. Mastectomy may be suggested if there are several areas of DCIS in the breast or if there is a lot of DCIS within the breast. It may also be recommended if radiation therapy is not possible.

Bilateral mastectomy

The surgical removal of both breasts is called a double mastectomy or bilateral mastectomy.

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COMET STUDY – THANK YOU EMAIL THAT IS SENT 2 MONTHS PRIOR TO EACH ANNUAL SURVEY

From: COMET Survey <COMETsurvey@unc.edu>

Subject: Thank you for participating in the COMET study

Email body:

Dear {{FIRSTNAME e.g. Sue}},

We very much appreciate your contributions to the COMET study! We would like to thank you for the time and effort you have put towards completing the study surveys in the past year. Your answers to these questions will provide very important information about the experience of women receiving care for DCIS. This information is highly valued by the COMET study team

You will receive a survey once a year (annually). Your next survey will be sent to you in 2 months. If you have any questions please contact your study doctor.

Thanks again for participating in the COMET study.

Sincerely,

Dr. Shelley Hwang and the COMET study team

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