FAQs

Can I stop being in the study?
Yes. You can decide to stop at any time, however your ability to stay in the study for the full 10 years will enable us to evaluate the long term effects of this new device and procedure.

What side effects or risks can I expect from being in the study?
*You may have side effects while in the study. Everyone taking part in t*he study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious.

Where can I find more information about this study?
Go to http://www.ClinicalTrials.gov, and enter study identifier: NCT01644669

Tri-City Medical Center
ADVANCED HEALTH CARE...FOR YOU

Xoft, a subsidiary of iCAD Inc.
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Tri-City Medical Center
ADVANCED HEALTH CARE...FOR YOU

The "IORT" Trial

A Safety & Efficacy Study of IORT Using the Xoft® Axxent® eBx® System at the Time of Breast Conservation Surgery for Early Stage Breast Cancer

(CTPR-0009)

Xoft®
a subsidiary of iCAD®

MC454 Rev A.

Principal Investigator at Tri-City

Tri-City Medical Center
ADVANCED HEALTH CARE...FOR YOU

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Why is this study being done?

The purpose of this study is to compare the effects, good and/or bad, of giving a new form of radiation therapy, called intra-operative radiation therapy (IORT), after breast conservation surgery (Lumpectomy) for your early-stage breast cancer. The standard treatment after a Lumpectomy for your type of breast cancer is external beam radiation. Standard external beam radiation is given to the whole breast. This can take up to 5 to 7 weeks of daily (Monday through Friday) visits to the hospital. Although external beam radiation is known to considerably reduce the risk of your breast cancer coming back, a few patients in every hundred will have a recurrence of their cancer in the treated breast. Over the last few years, a new device/procedure has been developed that delivers the radiation therapy directly to the tumor bed immediately after the tumor is removed in the operating room. This new device/procedure delivers less radiation to the other organs around the breast, like your heart and lungs. This new procedure is called intra-operative radiation therapy, or IORT, as it takes place in the operating room at the same time that your tumor is surgically removed. This study will assess whether this new device/procedure (IORT) is as effective as the standard 5 to 7 week course of external beam radiation after surgery. You will receive this new procedure (IORT) using the new device at the time of your Lumpectomy surgery.

Before you begin the study

1. History and physical exam, including breast exam
2. Pregnancy test (if you are a woman of child-bearing potential)
3. Biopsy of your breast cancer (a sample of tissue will be taken from your cancer to be examined under a microscope)
4. Mammogram (a low-dose x-ray exam of both breasts to look for changes that are not normal)

Once enrolled

1. Cosmesis assessment
2. Quality of Life Questionnaire

Day of surgery

1. Lumpectomy
2. Ultrasound
3. Intra-Operative Radiation Treatment-IORT
4. Upon completion of procedure, study subject returns home.

Study Visits after your treatment

1 month after your treatment:
Treatment-related history and physical exam
Quality of Life Questionnaire

6 months after your treatment:
Treatment-related history and physical exam
Mammogram of the treated breast
Evaluation of the physical appearance of both breasts (cosmesis)
Quality of Life Questionnaire

12 months after your treatment:
Treatment-related history and physical exam
Mammogram of both breasts
Evaluation of the physical appearance of both breasts (cosmesis)
Quality of Life Questionnaire

18 months after your treatment:
Treatment-related history and physical exam
Mammogram of the treated breast
Evaluation of the physical appearance of both breasts (cosmesis)
Quality of Life Questionnaire

Yearly for 10 years:
Treatment-related history and physical exam
Mammogram of both breasts
Evaluation of the physical appearance of both breasts (cosmesis)
Quality of Life Questionnaire