Making Choices

Deciding whether to join the IBIS-II Prevention study

A Decision Aid for Women at Increased Risk of Breast Cancer
Making Choices

Deciding whether to join the IBIS-II Prevention study
A Decision Aid for Post-Menopausal Women
at Increased Risk of Breast Cancer
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Introduction

A substantial number of women are at increased risk of developing breast cancer. Research continues to find ways of lowering this risk.

You have been invited to consider taking part in the International Breast Cancer Intervention Study-II (IBIS-II) Prevention study investigating the role of anastrozole (also known as Arimidex®) in reducing the risk of breast cancer in post-menopausal women, who are at elevated risk of the disease. Anastrozole already has an established role in the treatment of invasive breast cancer. This booklet is designed to assist you in deciding whether or not to take part in the IBIS-II study as one of your risk management options. We explain your current options and offer advice on how to make the decision that best suits you.

At the back of the booklet, you will find a page labelled “Your Notes” for you to write down questions to ask your doctor or research nurse. A glossary of medical terms and words used in clinical trials is also included. For more detailed information about any of the issues raised, please see the Participant Information Sheet for the IBIS-II Prevention study.

While reading the entire booklet may help you to understand your risk management options, it is not essential. However, we think you will find the sections on potential benefits and risks of management options particularly useful. The diagrams are included to complement the text - it is not necessary to read both. The worksheets are optional; you do not have to complete them.

Whether or not you decide to participate in the IBIS-II Prevention study, you will receive the very best care.
Understanding breast cancer risk

In this booklet, we use “risk” to mean the likelihood of developing invasive breast cancer. Everyone has some chance of developing breast cancer at some time in their life (including men).

Increased risk of breast cancer

Some people are more likely than others to develop breast cancer for various reasons, and these people are said to be at an increased risk. There are two major risk factors known to increase the risk of breast cancer – being female, and being of an older age.

Other risk factors include:

- Having a family history of breast cancer
- Having had certain previous breast conditions
- Never having had children
- Being 30 years or older at the birth of their first child
- Going through menopause after the age of 55
General population breast cancer risk

In developed countries, close to 10 out of 100 women will develop breast cancer at some point in their life (these figures are averages).

What is your risk of developing breast cancer in the future?

Your risk is at least twice that of the general population. Your precise risk will depend on the number and degree of risk factors that apply to you. Your doctor can tell you more about your precise risk.

If breast cancer develops, there is an excellent chance that this can be detected early and treated effectively so the majority of women can be cured and return to their normal life.
What can you do to decrease your risk of breast cancer?

Since you are at an increased risk of developing breast cancer, you may want to consider options you can take to minimise this risk. The following pages will explore some of the advantages and disadvantages of these options:

Option I
STANDARD CARE

Option II
CLINICAL TRIAL

RISK MANAGEMENT
(This will be discussed in consultation with your usual doctor.)

RISK MANAGEMENT
on the IBIS-II Prevention study
(for 5 years)

randomly assigned to

Anastrozole OR Placebo

Regardless of which option you choose, your doctor will ensure you get the best medical care.
Option I
Standard care: Risk management

You may choose to continue with standard risk management, which usually includes mammographic screening each year and regular clinical examinations. This helps to ensure any potential problems are identified as early as possible. In addition to this, other less known options exist for women at elevated risk of breast cancer, such as preventive mastectomy (reducing risk by about 95%) or chemoprevention (reducing risk by about 50%). Your doctor will discuss this with you in more detail.

What are some of the “PROS” of this option?

- Increased monitoring gives you a good chance of detecting any changes in breast tissue early
- You would not have side effects that may occur with taking medication such as anastrozole
- There is no “daily reminder” of the threat of cancer by taking a pill

What are some of the “CONS” of this option?

- Mammograms and clinical examinations may alert you and your doctor to the fact that there is something wrong, but they do not prevent or reduce the risk of developing breast cancer and it is important to know they are not 100% accurate
- You may feel that you have not done enough to maximise your chances of preventing breast cancer
- You may not have the reassurance of taking a daily pill to prevent breast cancer
Option II

IBIS-II Prevention study: Anastrozole or Placebo

The second option is to participate in the IBIS-II Prevention clinical trial. This research study investigates whether treatment with anastrozole is effective in preventing women at increased risk from developing breast cancer, without many adverse side effects. Anastrozole is described in more detail on page 14.

What is a clinical trial?

Clinical trials are a vital part of research into new and more effective medical treatments. Treatments used today (i.e. current standard treatments) have come from testing in clinical trials in the past. For some people, however, clinical trials raise fears of “experimentation” and “being a guinea pig”. Understanding more about clinical trials may reduce these concerns.

Strict controls govern how clinical trials are conducted. Each clinical trial must be approved by an ethics committee. This committee makes sure that the rights of the study participants are protected. New treatments are only assessed in clinical trials after years of extensive testing in laboratories where their safety and effectiveness have been proven. As a result much is already known about the benefits and risks of treatments offered within clinical trials. Sometimes the medication used in a clinical trial is not “new”, it is simply being used in a different way. In some cases, as with anastrozole, the drug may have already been shown to be effective for treating breast cancer, and safe for other groups of patients in earlier clinical trials.
What is a randomised double-blind study?

In a randomised clinical trial, two groups are needed to see whether the new treatment, or prevention strategy, is better than the standard care. The treatment, or intervention, each participant receives (either the standard or new treatment) is determined by chance (using a computer). If either participants or doctors were to choose which treatment will be received, participants who receive the “new drug” may be different (for example fitter, or younger) from participants who do not. Randomisation makes sure that both study groups are as similar as possible. This gives a more reliable picture of the effects of the treatments.

When no standard treatment exists, studies compare a new treatment with a placebo. A placebo is a tablet that looks like the trial medication but contains no active ingredients. Both medications look the same so no one can tell which is being taken. In a randomised double-blind study, neither the doctor nor the participant knows who is receiving the placebo or the newer treatment. It is important that the side effects reported by participants and their doctors are not based on what they expect to happen. If participants know that they are taking the new treatment, they might expect it to work better. If they expect it to work well they may report hopeful signs and not report unpleasant effects. This would bias the trial by making the results of the new treatment look better than they really are. The study co-ordinating centre can find out who is receiving which treatment, so should there be a medical need, this information is readily available to the woman’s doctor. All participants are carefully monitored during the study. Any participant is free to withdraw from the study at any time.
Why do people take part in a trial?

- They may receive a newer treatment that is not yet available to the general public and that may be more effective than the treatments currently recommended.

- To benefit future generations.

- To give themselves the best chance of reducing the risk of getting a cancer or of the cancer coming back.

- They appreciate the extra personalised care and attention given by research nurses and treating doctors. It has been shown that people receiving treatment on trials do just as well as, or better than those getting the same treatment outside of a clinical trial.

Why do people not take part in a trial?

- They prefer to decide on a treatment with their own doctor.

- They do not want to take a treatment that is still being investigated.

- They do not like the uncertainty of not knowing which treatment they are receiving.

- They may think a trial takes too long.
What is the IBIS-II Prevention study?

IBIS-II Prevention is an international study investigating the role of a new treatment (anastrozole) in reducing the risk of breast cancer in post-menopausal women who have an increased risk of the disease. The study will involve more than 6,000 women worldwide.

Why is the IBIS-II Prevention study being done?

The IBIS-I Prevention study which commenced in 1992, compared the anti-oestrogen drug tamoxifen with a placebo in healthy women at increased risk of breast cancer. IBIS-I showed that tamoxifen reduces the incidence of breast cancer by about a third in these women (see page 16), and that the benefit lasts for at least 10 years.

However, some women taking tamoxifen developed some side-effects which means that it may not be suitable as a routine preventive treatment for all women with an increased risk of breast cancer.

Recent trials of a newer drug, called anastrozole, in women with early breast cancer, found that anastrozole was more effective than tamoxifen in preventing new cancers in the same breast, the opposite breast and elsewhere in the body. Anastrozole has also been shown to have fewer and potentially less serious side effects than tamoxifen.
How does the IBIS-II Prevention study work?

Women in the IBIS-II Prevention study will be randomly selected by a computer to be given either anastrozole or a placebo, so the effects of anastrozole can be determined (see diagram below). Neither you, your doctor or the medical team, can choose or will know which medication (anastrozole or placebo) you are taking until after the study is completed. However, this information can be obtained from the co-ordinating centre should there be a medical need or if you withdraw for any reason. You may withdraw from the study at any time you wish, or if a change in your condition suggests that would be best. You can be assured that leaving the study will not influence your relationship with the medical/research staff or your future medical treatment.

Whilst we know that anastrozole is effective as a treatment for breast cancer, its use as a preventive treatment in healthy women with an increased risk of this disease has not yet been investigated.

The aim of the IBIS-II Prevention study is to determine whether anastrozole is of benefit to women, like you, who have an increased risk of developing breast cancer.
Anastrozole
(also known as Arimidex®)

What is it?

Anastrozole is a new type of treatment which has been successfully used to treat oestrogen sensitive (ER+) advanced breast cancers in post-menopausal women, during the last decade. Recent results from a research study (called ATAC - see pages 15-16), and other studies which have included women who developed early invasive breast cancer, indicate that anastrozole is significantly more effective than tamoxifen in reducing the risk of the breast cancer coming back. Anastrozole was also about twice as effective as tamoxifen in preventing a new breast cancer developing in the opposite breast. Anastrozole seemed to produce fewer short-term side effects than tamoxifen. The IBIS-II Prevention study will assess whether anastrozole is of benefit to women like you, who have an elevated risk of breast cancer. Longer-term benefits and side effects of anastrozole are being investigated in clinical treatment trials.

How is it taken?

Anastrozole is taken as a tablet once a day for 5 years. At the end of the 5-year study your treatment will stop, and your progress will be monitored for another 5 years. Participants in the study will receive their medication (anastrozole or placebo tablet) free of charge for the length of the treatment phase of the study (5 years).

How does it work?

Anastrozole is a treatment belonging to a group of drugs called aromatase inhibitors. It is designed to reduce the amount of oestrogen produced in post-menopausal women. Whilst tamoxifen binds to the oestrogen receptors in the cell, anastrozole blocks the production of oestrogen in the body, thus reducing oestrogen to almost undetectable levels. As a result it may stop existing breast cancers growing and the development of new oestrogen sensitive (ER+) breast cancers may be prevented.
Anastrozole: Potential BENEFITS

Potentially more effective against breast cancer than tamoxifen, with fewer side effects

The ATAC study compared the effects of anastrozole and tamoxifen in 9,366 post-menopausal women with early stage oestrogen-sensitive invasive breast cancer (women had been monitored for 5 years). This study looked at how effective each treatment is in preventing breast cancer from returning, either in the breast where the cancer developed originally, or in the other breast.

In this study, women who took anastrozole had fewer incidences of breast cancer returning and fewer side effects, compared to women who took tamoxifen. Anastrozole was also about twice as effective as tamoxifen in preventing a new breast cancer developing in the opposite breast. For instance, out of 1,000 women with early stage breast cancer who received anastrozole, 35 women developed secondary (new) cancer in the opposite breast. In comparison, out of 1,000 women who received tamoxifen, 59 women developed secondary (new) cancer in the opposite breast (see diagram on page 16).

Anastrozole is effective in reducing the risk of breast cancer coming back. The IBIS-II Prevention Study will indicate whether anastrozole is effective in preventing breast cancer development in women at increased risk of breast cancer.
Anastrozole: Potential BENEFITS

IBIS-I prevention study

Women at ELEVATED RISK of breast cancer

In the IBIS-I study, 132 women who received the placebo developed hormone sensitive invasive breast cancer, compared to 87 women who received tamoxifen.

ATAC treatment study

Women with EARLY STAGE breast cancer

In the ATAC study, 59 women who received tamoxifen developed new invasive breast cancer in the opposite breast, compared to 35 women who received anastrozole.

Previous studies indicate that tamoxifen is more effective than a placebo for preventing breast cancer. Other studies indicate that anastrozole is more effective than tamoxifen in preventing the development of new breast cancer in women previously diagnosed with early breast cancer.
Anastrozole: SIDE EFFECTS and potential RISKS

Although most women find anastrozole easy to tolerate, it can have some adverse side effects. These, however, are rarely serious.

COMMON SIDE EFFECTS
(Between 1 in 10 women and 1 in 100 experience these)

- **Menopausal-like symptoms: Hot flushes and vaginal dryness**
  Hot flushes are fairly common side effects but are usually milder than those experienced with tamoxifen. Vaginal dryness is a common side effect which may require additional care. HRT cannot be taken to ease these side effects whilst on the IBIS-II Prevention study. Alternative treatments such as herbal medicine can be used.

- **Joint/back pain or stiffness**
  Some women who have taken anastrozole have noticed that they felt mild to severe joint/back pain and stiffness in the morning but this disappeared after they started moving around.

- **Carpal Tunnel Syndrome**
  Some women may experience pressure on a nerve at the wrist causing pain, weakness or numbness. This condition, known as Carpal Tunnel Syndrome, can be treated.

These side effects are usually temporary and disappear when anastrozole is no longer taken.
Anastrozole: SIDE EFFECTS and potential RISKS

COMMON SIDE EFFECTS (cont.)

• **Fractures**  
Oestrogen is necessary to maintain bone density. Since anastrozole directly reduces oestrogen levels, it may lead to loss of bone density. As a result, the risk of fractures may increase whilst taking anastrozole, but will return to normal once anastrozole is no longer taken.

• **Osteoporosis**  
Osteoporosis affects 45 in every 100 women who are 50 years of age or older, during their lifetime. For some women taking anastrozole the risk of fractures and osteoporosis appears to increase and this is currently being investigated in a number of studies. If you choose to take part in the IBIS-II Prevention study, your bone density will be assessed, and if osteoporosis is detected treatment for this will be recommended.

VERY RARE but potentially SERIOUS SIDE EFFECTS

• **Allergic skin reactions**  
*(less than 1 in 10,000 women experience this)*

Very rarely women develop a severe skin reaction in the form of lesions, blisters or ulcers. Contact your study doctor immediately if you develop any of these symptoms.
Anastrozole: SIDE EFFECTS and potential RISKS

Each diagram represents 100 women. The light-green shaded area shows the number of women in the general population who may develop each of the presented symptoms over 5 years. The darker green shaded area shows the number of additional women who may develop each of the presented symptoms over 5 years because they are taking ANASTROZOLE.

Compared to the general population, an additional 10 women taking ANASTROZOLE may experience:

- Hot flushes

Compared to the general population, an additional 7 women taking ANASTROZOLE may experience:

- Joint pain or stiffness
Anastrozole: SIDE EFFECTS and potential RISKS

Compared to the general population, an additional 4 women taking ANASTROZOLE may experience:

Fractures

Compared to the general population, an additional 2 women taking ANASTROZOLE may experience:

Carpal Tunnel Syndrome

What to do if side effects become too bothersome

It is not expected that taking part in this clinical trial should cause you undue discomfort. However, should the side effects become too unpleasant, it is strongly recommended that you discuss available treatment options with your study co-ordinator or doctor. If you become concerned about a symptom, a “treatment holiday” of up to three months may be possible. To protect your health, it is strongly advised that any changes to the treatment program are made by your study doctor.
Anastrozole: Summary of BENEFITS & RISKS

Benefits: 

<table>
<thead>
<tr>
<th>Breast Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>++ Known to reduce the risk of breast cancer coming back</td>
</tr>
<tr>
<td>? (+) Potential ability to prevent or delay breast cancer developing for the first time; this needs further confirmation</td>
</tr>
</tbody>
</table>

Risk: 

<table>
<thead>
<tr>
<th>Bone Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Increases the risk of bone density loss</td>
</tr>
</tbody>
</table>

+ ----- Known benefit 
? (+) ----- Potential benefit 
- ----- Known risk
What is involved if you take part in the study?

If you join the IBIS-II Prevention study, your wellbeing will be closely monitored and all information regarding your condition will be carefully and confidentially recorded. You will have some additional examinations and tests at no financial cost to you. Although they can be inconvenient, these tests make sure you are thoroughly monitored throughout your treatment.

Screening mammograms & clinical examinations

Screening mammograms and clinical examinations will be done at least once a year. You may already be receiving this same level of screening and clinical examination as you are at increased risk.

Medication

You will be given a 6-month supply of tablets in numbered containers. Extra tablets will be included to allow for some delay in the next appointment (e.g. due to travel or sickness). Whilst on the study, you will be asked to take one tablet each day. You will be taking anastrozole or a placebo. A placebo is a tablet that looks like the trial medication but contains no active ingredients. The placebo tablet is used to ensure that neither you nor your doctor knows which treatment you are receiving. However, since the tablets you receive may contain lactose and gluten, you should not participate in the study if you suffer from lactose or gluten intolerance. You do not have to change your diet or lifestyle whilst taking the medication.
Regular support

You will have access to a support team who can provide information on a regular basis during the study. This team may include your study doctor and your IBIS-II study co-ordinator. During the first year of the study, you will be asked to come to the clinic (at 6 months and 12 months), for a breast examination and to check your general health. After the first year of the study, your study co-ordinator will arrange your annual follow-up visits. With your permission, your GP will also be informed about the study and will be able to provide additional information should you need any.
Tests & Questionnaires whilst on the IBIS-II study

Bone density tests and advice for healthy bones

At the start of the study, you will have an x-ray of your spine and a bone mineral density test (DXA scan) to assess the condition of your bones (unless you have already had one during the past 2 years).

Throughout the study you will be offered advice on how to maintain healthy bones. This advice is the same as for similar women in the community not on the trial. The advice covers exposure to sunlight, weight bearing exercises, Calcium and Vitamin D supplements (you will need to pay for any supplements you use).

Blood samples

When you join the study a blood sample of 20ml (about 4 teaspoons) will be taken. A further 10 ml blood sample (about 2 teaspoons) will be taken at years 1 and 5 of the study.

Questionnaires

After the 5th year of treatment, you will be asked to complete questionnaires annually for another 5 years in order to monitor your health and wellbeing following the treatment.

You will be able to contact your study doctor or study co-ordinator between your visits.
Summary table of follow-up schedule whilst on the study

<table>
<thead>
<tr>
<th>Contact by IBIS-II study co-ordinator*</th>
<th>0-1 year</th>
<th>2-5 years</th>
<th>6-10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Every 6 months</strong></td>
<td>Every 6 months or 12 months (your choice)</td>
<td>Once a year</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical examination</strong></td>
<td>At study entry, 6 months and 1 year</td>
<td>Once a year</td>
<td>Will be discussed with study doctor</td>
</tr>
<tr>
<td><strong>Mammogram</strong></td>
<td>Possibly at study entry; At 1 year</td>
<td>Once a year</td>
<td>Once a year</td>
</tr>
<tr>
<td><strong>Blood sample</strong></td>
<td>At study entry and 1 year</td>
<td>At year 5</td>
<td>--</td>
</tr>
<tr>
<td><strong>Bone density tests</strong></td>
<td>At study entry (unless one done within last 2 years)</td>
<td>Only if recommended by your GP or study doctor</td>
<td>Only if recommended by your GP or study doctor</td>
</tr>
<tr>
<td><strong>Questionnaire</strong></td>
<td>--</td>
<td>--</td>
<td>Once a year</td>
</tr>
</tbody>
</table>

*You can contact your study co-ordinator at any time*
Summary of Option II:
Risk management on clinical trial

What are some “PROS” of the “risk management on clinical trial” option?

• I want to maximise my chances and by taking part in a clinical trial, I may be allocated to the newer treatment (anastrozole) which may be more effective in preventing the development of breast cancer than the standard management.

• I will be closely monitored on the trial and be supported by a research team. I will be contacted to arrange my screening follow up appointments. I will have medical tests arranged for me. My bone density will be assessed.

• Irrespective of which tablet I am given, I will be receiving excellent treatment and attention.

• I will not have to pay for the drug I am receiving whilst on the trial.

• My observations will be helping scientific research worldwide, and other women in the future, and probably help to save lives.

What are some “CONS” of the “risk management on clinical trial” option?

• I will not know if I am allocated the new drug until the end of the study.

• I may have to deal with side effects (see pages 17-20).

• I will have to complete questionnaires and have three blood tests.

• I could be allocated to a treatment which may potentially increase my risk of osteoporosis.
Making a decision

The previous pages have outlined the main risk management options available to you now. The following steps may help you to make the decision whether or not to join the IBIS-II Prevention study.

The decision-making process can be helped by following these 6 steps:

1. Understand your diagnosis and your future risk of breast cancer as fully as you can
2. Understand your options for further management and the risks and benefits of these options
3. Review the pros and cons of these options
4. Assess how important the pros and cons are to you
5. Prioritise the pros and cons of the study for you (and your family)
6. Get more information/clarification about any uncertain areas

You have already gone through steps 1-3. To help you complete steps 4-6 and come to the decision that suits you best, we have included examples of how some women reached their decision. This information is presented in a work-sheet format that you can use (see overleaf).

You will receive excellent care whether you choose standard care or to take part in the clinical trial.
Worksheets

This worksheet starts with examples of how some women view the pros and cons of the standard treatment and the IBIS-II Prevention study (next 2 pages). This is followed by your own worksheet, where we invite you to list the pros and cons of the statements in the boxes and rate how important these are to you.

Each statement has three options underneath it, each describing a level of concern/benefit that you may have about the issue raised by the statement. By circling one of the options, you can indicate (and see at a glance) how important each issue is to you:

- Circling **Big Concern/Benefit** => indicates that the issue is very important to you,
- Circling **Small Concern/Benefit** => indicates that the issue is somewhat important,
- Circling **No Concern/Benefit** => indicates that the issue is not important to you

The column with the greater number of “Big Concern/Benefit” options circled may indicate that you are more inclined to choose that option. There is a space for you to add your own pros and cons and rate their importance.

**Example**
One of the cons of participating in the IBIS-II Prevention study are the side-effects of anastrozole. If a woman feels that she will be able to handle these (i.e. this issue is only a small concern to her), she circles “Small Concern” under this statement.

```
Side effects from anastrozole, if I get it

No Concern  [ ] Small Concern  [X] Big Concern

“I think I’ll be able to handle that”
```

At the bottom of the worksheet you can indicate (by circling one of the 1-5 stars) which way you are leaning in your decision:

- Participating in the study
- Not participating in the study

By circling the 3rd star, this woman is showing she is still unsure whether or not to join the trial.
Anna’s worksheet: “Will the IBIS-II Prevention study suit me?”

**PROS of the study**

- This may help future generations of women
  “I can make a difference. My daughter may benefit”
  - No Benefit
  - Small Benefit
  - Big Benefit

- I will get excellent care on the trial
  “It is good to know I am getting cutting edge care”
  - No Concern
  - Small Concern
  - Big Concern

- I might get access to a new and better drug
  “It is good to know I am getting every chance”
  - No Concern
  - Small Concern
  - Big Concern

**CONS of the study**

- I may get a drug untested in women with an elevated risk of breast cancer
  “This does not concern me”
  - No Concern
  - Small Concern
  - Big Concern

- I won’t know if I am getting the placebo or anastrozole
  “I understand why this is necessary”
  - No Concern
  - Small Concern
  - Big Concern

- Side effects from anastrozole, if I get it
  “I think I will be able to handle that”
  - No Concern
  - Small Concern
  - Big Concern

**Other:**

- No Concern
- Small Concern
- Big Concern

**Participating in the study**

**Not participating in the study**

Any further questions? Will I get access to the tablets once the study is over?

How is Anna leaning? Participating in the study ★ ★ ★ ★ ★ Not participating in the study

* (circle one star only)

(Anna is leaning towards joining the study)
Dianne's worksheet: “Will the IBIS-II Prevention study suit me?”

**Pros of the study**

- This may help future generations of women
  “I am more important right now.”
  - No Benefit
  - Small Benefit
  - Big Benefit

- I will get excellent care on the trial
  “I get excellent care from my doctor now”
  - No Benefit
  - Small Benefit
  - Big Benefit

- I might get access to a new and better drug
  “But it might not be better”
  - No Benefit
  - Small Benefit
  - Big Benefit

**Cons of the study**

- I may get a drug untested in women with an elevated risk of breast cancer
  “Am I prepared to take that risk?”
  - No Concern
  - Small Concern
  - Big Concern

- I won’t know if I am getting the placebo or anastrozole
  “I’d prefer to know”
  - No Concern
  - Small Concern
  - Big Concern

- Side effects from anastrozole, if I get it
  “I don’t want to have hot flushes”
  - No Concern
  - Small Concern
  - Big Concern

**Other:**

- “I don’t like blood tests”
  - No Concern
  - Small Concern
  - Big Concern

**Participating in the study**

**Not participating in the study**

**Any further questions?**
Can I continue taking the drug when the study is over?

**How is Dianne leaning?**

- Participating in the study ⭐⭐⭐️⭐️⭐️
- Not participating in the study

*(circle one star only)*

*(Dianne is leaning towards NOT joining the study)*
Your worksheet: “Will the IBIS-II Prevention study suit me?”

PROS of the study

This may help future generations of women

I will get excellent care on the trial

I might get access to a new and better drug

Other:

CONS of the study

I may get a drug untested in women with an elevated risk of breast cancer

I won’t know if I am getting the placebo or anastrozole

Side effects from anastrozole, if I get it

Other:

Any further questions?

What are YOU leaning towards?

Participating in the study ★ ★ ★ ★ ★

Not participating in the study

(circle one star only)
Further contacts

Many women seek information on the internet about breast cancer treatments, research, clinical trials and support services. However not all information reported is accurate or reliable.

Listed below are a number of websites that are prepared by cancer organisations. As the information can only be general and not specific to your situation, it is important to discuss any questions you have with your treating doctor.

Australia and New Zealand

Australian New Zealand Breast Cancer Trials Group  www.anzbctg.org
Breast Cancer Institute of Australia  www.bcia.org.au
IBIS-II co-ordinating centre, UK  www.ibis-trials.org
National Breast Cancer Centre, Australia  www.nbcc.org.au
The Cancer Council Australia  www.cancer.org.au

The IBIS-II Prevention Research Protocol, Decision Aid Booklet, and Questionnaire have been reviewed and endorsed by the ANZ BCTG Consumer Advisory Panel.
References


• The ATAC (Arimidex, Tamoxifen Alone or in Combination) Trialists’ Group. Results of the ATAC (Arimidex, Tamoxifen Alone or in Combination) trial after completion of 5 years’ adjuvant treatment for breast cancer. *The Lancet* 2005; 365: 60-62.


Glossary of terms

**Advanced breast cancers**: Cancer cells have spread past the breast and armpit to other parts or organs of the body.

**Anastrozole (also known as Arimidex®)**: A new aromatase inhibitor therapy (tablets) for treating breast cancer which stops the body making female sex hormones (oestrogen).

**Aromatase inhibitors**: Drugs that block the enzyme aromatase in post-menopausal women. They lower the amount of oestrogen in your body.

**Bone density**: How closely compacted the substance is inside your bones. A measure of bone strength.

**Bone mineral density test**: An X-ray to determine the amount of calcium and other minerals in the bone, used to diagnose osteoporosis.

**Cancer**: A group of diseases in which malignant cells grow out of control and may spread to other parts of the body.

**Carpal Tunnel Syndrome**: Pressure on a nerve at the wrist causing pain, weakness or numbness. This condition can be treated.

**Clinical trial**: A scientific test of the effectiveness and safety of a drug involving consenting human participants.

**Diagnosis**: Process of identifying a disease from symptoms & tests.

**ER**: Oestrogen receptor, a part of the cell where oestrogen attaches.

**Hormone sensitive breast cancer**: A breast cancer that grows in response to the female hormone oestrogen.

**HRT (Hormone Replacement Therapy)**: Medication containing one or more female hormones, often used to treat symptoms of menopause.
Invasive breast cancer: Breast cancer which has spread beyond the tissue in which it developed and is growing into surrounding, healthy tissues.

Mammogram: A low-dose X-ray of the breast to check for any abnormal tissue.

Oestrogen: Female sex hormones produced primarily by the ovaries in pre-menopausal women and by the aromatase enzyme in post-menopausal women.

Osteoporosis: A condition that weakens bones, and makes them more prone to fracture.

Menopause: The time in a woman’s life when the ovaries cease to function and menstrual periods stop for at least 12 months.

Placebo: A tablet that looks like the trial medication but contains no active ingredients.

Post-menopausal: The period in a woman’s life after the menopause.

Standard risk management: The current way to minimise your risk of breast cancer.

Tamoxifen: A long-established treatment for breast cancer, which stops the action of oestrogen on cancer cells.

Treatment holiday: Stopping the treatment for a period of time.
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This Decision Aid was conceived and developed by a team from the Medical Psychology Research Unit at the University of Sydney, led by Professor Phyllis Butow and Dr Ilona Juraskova. Noteworthy contributors include Ms Anna-Lena Lopez and Mr Benaud Smith. Graphic design was undertaken by Ben Carew who can be contacted on +61 2 8307 3800.

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