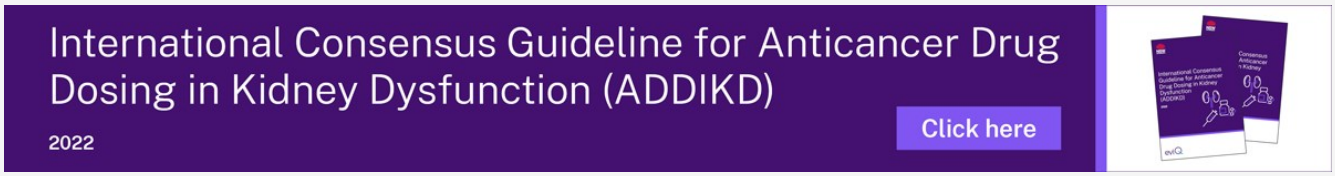
Breast adjuvant anastrozole

ID: 19 v.5 **Endorsed** Essential Medicine List

Check for clinical trials in this patient group. Link to Australian Clinical Trials website

The anticancer drug(s) in this protocol may have been included in the ADDIKD guideline. Dose recommendations in kidney dysfunction have yet to be updated to align with the ADDIKD guideline. Recommendations will be updated once the individual protocol has been evaluated by the reference committee. For further information refer to the ADDIKD guideline. To assist with calculations, use the eviQ Estimated Glomerular Filtration Rate (eGFR) calculator.



Treatment schedule - Overview

Drug	Dose	Route
Anastrozole	1 mg ONCE a day	PO

Continuous daily to complete a total of 5 to 10 years of adjuvant endocrine therapy

Drug status: Anastrozole is a PBS restricted benefit

Cost: ~ $20 per month

Treatment schedule - Detail

The supportive therapies (e.g. antiemetics, premedications, etc.), infusion times, diluents, volumes and routes of administration, if included, are listed as defaults. They may vary between institutions and can be substituted to reflect individual institutional policy.

*Antiemetics if included in the treatment schedule are based upon recommendations from national and international guidelines. These are **defaults only** and may be substituted to reflect individual institutional policy. Select here for recommended doses of alternative antiemetics.*

Continuous treatment		
Anastrozole	1 mg (PO)	ONCE a day

Continuous daily to complete a total of 5 to 10 years of adjuvant endocrine therapy

Indications and patient population

- Hormone receptor positive invasive breast cancer in post-menopausal women for a total of 5 to 10 years of adjuvant endocrine therapy.[1, 2]

Clinical information

Emetogenicity MINIMAL	No antiemetics should be routinely administered before treatment in patients without a history of nausea and vomiting. If patients experience nausea and/or vomiting, consider using the low antiemetic prophylaxis regimen.
Bone mineral density (BMD)	Baseline BMD and repeat as clinically indicated. Lifestyle modification including regular exercise, particularly weight bearing exercises should be encouraged.
Supplements	Consider daily oral supplements of at least calcium 500 mg and vitamin D 400 International Units for the duration of the therapy.
Oestrogen preparations	Oestrogen preparations should be avoided due to insufficient data on safety as systemic absorption of oestrogen may negate the effect of aromatase inhibitors. Minimal use of topical oestrogen therapies for vulvo-vaginal complaints may be considered.
Blood tests	LFTs, lipid studies, calcium and vitamin D at baseline and repeat as clinically indicated.

Dose modifications

Evidence for dose modifications is limited, and the recommendations made on eviQ are intended as a guide only. They are generally conservative with an emphasis on safety. Any dose modification should be based on clinical judgement, and the individual patient's situation including but not limited to treatment intent (curative vs palliative), the anti-cancer regimen (single versus combination therapy versus chemotherapy versus immunotherapy), biology of the cancer (site, size, mutations, metastases), other treatment related side effects, additional co-morbidities, performance status and patient preferences.Suggested dose modifications are based on clinical trial findings, product information, published guidelines and reference committee consensus . The dose reduction applies to each individual dose and not to the total number of days or duration of treatment cycle unless stated otherwise. Non-haematological gradings are based on Common Terminology Criteria for Adverse Events (CTCAE) unless otherwise specified. Renal and hepatic dose modifications have been standardised where possible. For more information see dosing considerations & disclaimer .

Renal impairment
No dose modifications necessary

Hepatic impairment	
Hepatic dysfunction	
Severe	Anastrozole has not been investigated in patients with severe hepatic impairment The potential risk / benefit to such patients should be carefully considered before administration of anastrozole

Interactions

Drug interactions in eviQ protocols are under review and being updated to align with current literature. Further site-wide updates and changes will occur in due course. References & Disclaimer

The drug interactions shown below are not an exhaustive list. For a more comprehensive list and for detailed information on specific drug interactions and clinical management, please refer to the specific drug product information and the following key resources:

- *MIMS - interactions tab (includes link to a CYP-450 table) (login required)*
- *Australian Medicines Handbook (AMH) – interactions tab (login required)*
- *Micromedex Drug Interactions (login required)*
- *Cancer Drug Interactions*
- *Cytochrome P450 Drug Interactions*

Anastrozole		
	Interaction	**Clinical management**
Tamoxifen	Reduced efficacy of anastrozole due to lowered plasma levels	Combination contraindicated
Oestrogen containing therapies	Negate the pharmacological action of anastrozole	Avoid combination (minimal use of topical oestrogen therapy for vulvo-vaginal complaints may be considered)

Administration

eviQ provides safe and effective instructions on how to administer cancer treatments. However, eviQ does not provide every treatment delivery option, and is unable to provide a comprehensive list of cancer treatment agents and their required IV line giving set/filter. There may be alternative methods of treatment administration, and alternative supportive treatments that are also appropriate. Please refer to the individual product information monographs via the TGA website for further information.

Administration

This is a continuous oral treatment

Safe handling and waste management (reproductive risk only)

Safe administration

Anastrozole

- administer orally ONCE a day
- to be swallowed whole with a glass of water
- can be taken with food or on an empty stomach
- if nausea develops, anastrozole may be taken with or after food or at night.

Note: missed doses should not be replaced; if a dose is forgotten or vomited, normal dosing should be resumed at the next scheduled dose.

Continue safe handling precautions (reproductive risk only) for 7 days after completion of drug(s).

Discharge information

Anastrozole tablets

- Anastrozole tablets with written instructions on how to take them.

Patient information

- Ensure patient receives patient information sheet.

Side effects

The side effects listed below are not a complete list of all possible side effects for this treatment. Side effects are categorised into the approximate onset of presentation and should only be used as a guide.

Immediate (onset hours to days)	
Headache	
Nausea and vomiting	

Early (onset days to weeks)	
Hot flushes	
Hyperlipidaemia and hypercholesterolaemia	Abnormally elevated levels of lipids and cholesterol in the blood.
Fluid retention and oedema	An excess amount of fluid around the cells, tissues or serous cavities of the body, leading to swelling.

Late (onset weeks to months)	
Arthralgia and myalgia	Generalised joint pain or and/or stiffness and muscle aches, often worse upon waking or after long periods of inactivity. Can improve with movement. May be mild or severe, intermittent or constant and accompanied by inflammation. Read more about arthralgia and myalgia
Vaginal atrophy	Read more about vaginal dryness

Delayed (onset months to years)	
Osteoporosis	

Evidence - Initial treatment

The evidence supporting this protocol is provided by a phase III multicentre international randomised trial (ATAC) involving 9366 patients comparing tamoxifen alone, anastrozole alone and the combination of anastrozole plus tamoxifen for 5 years for adjuvant treatment of postmenopausal women with early breast cancer.[3]

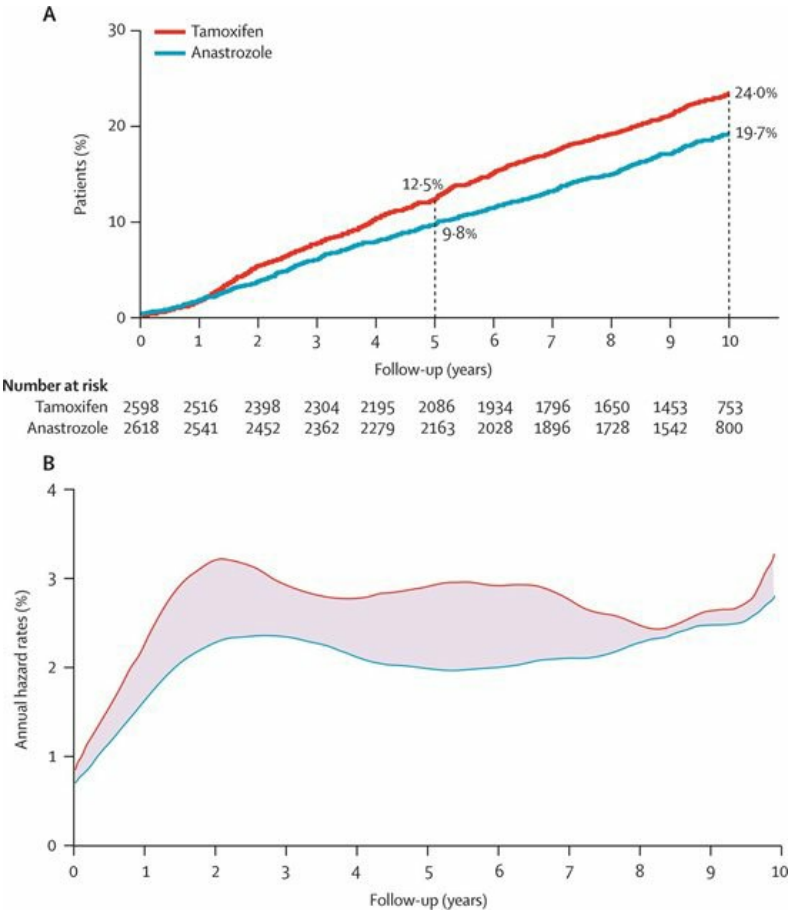
Between July 1996 and March 2000, 3125 patients were randomised to receive anastrozole 1 mg daily, 3116 tamoxifen 20 mg daily, and 3125 anastrozole 1 mg plus tamoxifen 20 mg daily for 5 years.

The primary endpoint was disease-free survival (DFS) and secondary endpoints were time to recurrence, time to distant recurrence, incidence of new contralateral primary breast tumours and overall survival.[3]

Efficacy

At the median follow up of 120 months, there were statistically significant improvements in the anastrozole group compared with the tamoxifen group for DFS (hazard ratio [HR] 0.91, 95% CI 0.83 - 0.99; *p*=0.04), time to recurrence (0.84, 0.75 - 0.93; *p*=0.001) and time to distant recurrence (0.87, 0.77 - 0.99; *p*=0.03). For hormone-receptor-positive patients (n=7839, 84%), the results were in favour of the anastrozole group for disease-free survival (HR 0.86, 95% CI 0.78 - 0.95; *p*=0.003), time to recurrence (0.79, 0.70 - 0.89; *p*=0.0002) and time to distant recurrence (0.85, 0.73 - 0.98; *p*=0.02). Absolute differences in time to recurrence between anastrozole and tamoxifen increased over time (2.7% at 5 years and 4.3% at 10 years) and recurrence rates remained significantly lower on anastrozole than tamoxifen after treatment completion (HR 0.81, 95% CI 0.67 - 0.98; *p*=0.03), although the carryover benefit was smaller after 8 years.[4]

Kaplan-Meier prevalence curves for time to recurrence in hormone-receptor positive patients[4]



Deaths after recurrence were not significantly lower with anastrozole than with tamoxifen over the 10 years of follow-up. In view of the significant reduction in distant recurrence, deaths after recurrence might become significantly lower with anastrozole than tamoxifen in the future, but further follow-up is needed for this endpoint.[4]

Toxicity

Overall, treatment-related serious adverse events were less common in the anastrozole group than the tamoxifen group (223 anastrozole vs 369 tamoxifen; OR 0.57, 95% CI 0.48 - 0.69; $p<0.0001$), but were similar after treatment completion (66 vs 78; OR 0.84, 95% CI 0.60 - 1.19; $p=0.3$). More fractures were reported during treatment in the anastrozole group than the tamoxifen group (451 vs 351; OR 1.33, 95% CI 1.15 - 1.55; $p<0.0001$) but were also similar after treatment completion (110 vs 112; OR 0.98, 95% CI 0.74 - 1.30; $p=0.9$; 10-year rate 2.0% vs 1.5%).[4]

The 10-year update also confirmed the overall incidence of new primary cancers to be similar in the two treatment groups (13.7% anastrozole vs. 13.9% tamoxifen). While differences in the rates of some new primary cancers were observed, including endometrial, contralateral breast, ovarian, melanoma, lung, colorectal and head and neck cancer, the differences were not statistically significant, with the exception of endometrial cancer, which showed a fourfold increase on tamoxifen; 6 (0.2%) vs. 24 (0.8%), $p=0.014$.[4]

Deaths in study population[4]

	Anastrozole (n=3125)	Tamoxifen (n=3116)
Total deaths	734 (23·5%)	747 (24·0%)
Deaths after recurrence	395 (12·6%)	441 (14·2%)
Deaths without recurrence	339 (10·8%)	306 (9·8%)
Cardiovascular	91 (2·9%)	95 (3·0%)
Cerebrovascular	33 (1·1%)	36 (1·2%)
Other cancer	108 (3·5%)	82 (2·6%)
Other	107 (3·4%)	93 (3·0%)

Table 3: Deaths in the full study population

Adverse events[5]

	Number of patients (%)		Odds ratio, anastrozole vs tamoxifen (95% CI)	p
	Anastrozole (n=3092)	Tamoxifen (n=3094)		
Hot flushes	1104 (35·7%)	1264 (40·9%)	0·80 (0·73–0·89)	<0·0001
Nausea and vomiting	393 (12·7%)	384 (12·4%)	1·03 (0·88–1·19)	0·7
Fatigue/tiredness	575 (18·6%)	544 (17·6%)	1·07 (0·94–1·22)	0·3
Mood disturbances	597 (19·3%)	554 (17·9%)	1·10 (0·97–1·25)	0·2
Arthralgia	1100 (35·6%)	911 (29·4%)	1·32 (1·19–1·47)	<0·0001*
Vaginal bleeding	167 (5·4%)	317 (10·2%)	0·50 (0·41–0·61)	<0·0001
Vaginal discharge	109 (3·5%)	408 (13·2%)	0·24 (0·19–0·30)	<0·0001
Endometrial cancer†	5 (0·2%)	17 (0·8%)	0·29 (0·11–0·80)	0·02
Fractures‡	340 (11·0%)	237 (7·7%)	1·49 (1·25–1·77)	<0·0001*
Hip	37 (1·2%)	31 (1·0%)	1·20 (0·74–1·93)	0·5
Spine	45 (1·5%)	27 (0·9%)	1·68 (1·04–2·71)	0·03*
Wrist/Colles	72 (2·3%)	63 (2·0%)	1·15 (0·81–1·61)	0·4
All other sites§	220 (7·1%)	142 (4·6%)	1·59 (1·28–1·98)	<0·0001*
Ischaemic cardio-vascular disease	127 (4·1%)	104 (3·4%)	1·23 (0·95–1·60)	0·1
Ischaemic cerebro-vascular events	62 (2·0%)	88 (2·8%)	0·70 (0·50–0·97)	0·03
Venous thrombo-embolic events	87 (2·8%)	140 (4·5%)	0·61 (0·47–0·80)	0·0004
Deep venous thrombo-embolic events	48 (1·6%)	74 (2·4%)	0·64 (0·45–0·93)	0·02
Cataracts	182 (5·9%)	213 (6·9%)	0·85 (0·69–1·04)	0·1

*In favour of tamoxifen. †n=2229 for anastrozole, 2236 for tamoxifen, excluding patients with hysterectomy at baseline, recorded at any time. ‡Patients with one or more fractures occurring at any time before recurrence (includes patients no longer receiving treatment). §Patients may have had one or more fractures at different sites.

Table: Prespecified adverse events on treatment or within 14 days of discontinuation

Cardiovascular, cerebrovascular and thromboembolic events for aromatase inhibitors compared to tamoxifen[6]

Trial	Trmt arms	Cardiovascular	Cerebrovascular	Thromboembolic
ATAC[4,33,76]	A vs. T	Ischemic cardiovascular disease: 4.1% vs. 3.4%, $p = 0.1$ Cardiovascular deaths: 2% vs. 1%, p = NR	Ischemic cerebrovascular events: 2.0% vs. 2.8%, $p = 0.03$ Cerebrovascular deaths: <1% vs. 1%, p = NR	Venous thromboembolic events: 2.8% vs. 4.5%, $p = 0.0004$, OR 0.61, 95% CI 0.46 to 0.80 Deep venous thromboembolic events: 1.6% vs. 2.4%, $p = 0.02$
BIG 1–98[6]	L vs. T	All cardiac events: 5.5% vs. 5.0%, $p = 0.48$ Ischemic heart disease: 2.2% vs. 1.7%, $p = 0.21$ Cardiac failure: 1.0% vs. 0.6%, $p = 0.14$ Other cardiovascular events: 0.8% vs. 0.2%, $p = 0.014$	Cerebrovascular accident or TIA: 1.4% vs. 1.4%, $p = 0.90$	Thromboembolic events: 2.0% vs. 3.8%, $p < 0.001$
IES[8]	T → E vs. T	Cardiovascular events: 20.8% vs. 18.9%, $p = 0.09$ Ischemic cardiovascular disease: 9.9% vs. 8.6%, $p = 0.12$	NR	Thromboembolic events: 1.9% vs. 3.1%, $p = 0.01$
ITA[9]	T → A vs. T	Cardiovascular diseases: 7.9% vs. 9.3%, $p = 0.04$	NR	NR
ABCSG-8/ARNO-95[10]	T → A vs. T	Myocardial infarction: <1% vs. <1%, $p = 1.0$	NR	Embolism: <1% vs. <1%, $p = 0.064$ Thromboses: <1% vs. <1%, $p = 0.034$[a]
MA.17[11]	T → L vs. T → placebo	Cardiovascular disease: 5.8% vs. 5.6%, $p = 0.76$ Myocardial infarction: 0.3% vs. 0.4% New or worsening angina: 1.2% vs. 0.9% Angina requiring PTCA: 0.1% vs. 0.3% Angina requiring CABG: 0.2% vs. 0.5%	Stroke/TIA: 0.7% vs. 0.6%	Thromboembolic event: 0.4% vs. 0.2%

Note: Significant differences are shown in bold face.
Abbreviations: →, followed by; A, anastrozole; ABCSG, Austrian Breast and Colorectal Cancer Study Group; ARNO, Arimadex/Nolvadex; ATAC, Arimidex , Tamoxifen, Alone or in Combination; BIG, Breast International Group; CABG, coronary artery bypass graft; CI, confidence interval; E, exemestane; IES, Intergroup Exemestane Study; ITA, Italian Tamoxifen Anastrozole; L, letrozole; NR, not reported; OR, odds ratio; PTCA, Percutaneous Transluminal Coronary Angioplasty; T, tamoxifen; TIA, Transient Ischemic Attack; Trmt, treatment; vs, versus.
[a] Favours anastrozole.

Evidence - Early switch

The supporting evidence for this treatment comes from the meta-analysis of three clinical trials: the Austrian Breast and Colorectal Cancer Study Group (ABCSG 8), Arimidex-Nolvadex (ARNO 95), and the Italian Tamoxifen Anastrozole (ITA) studies.[7]

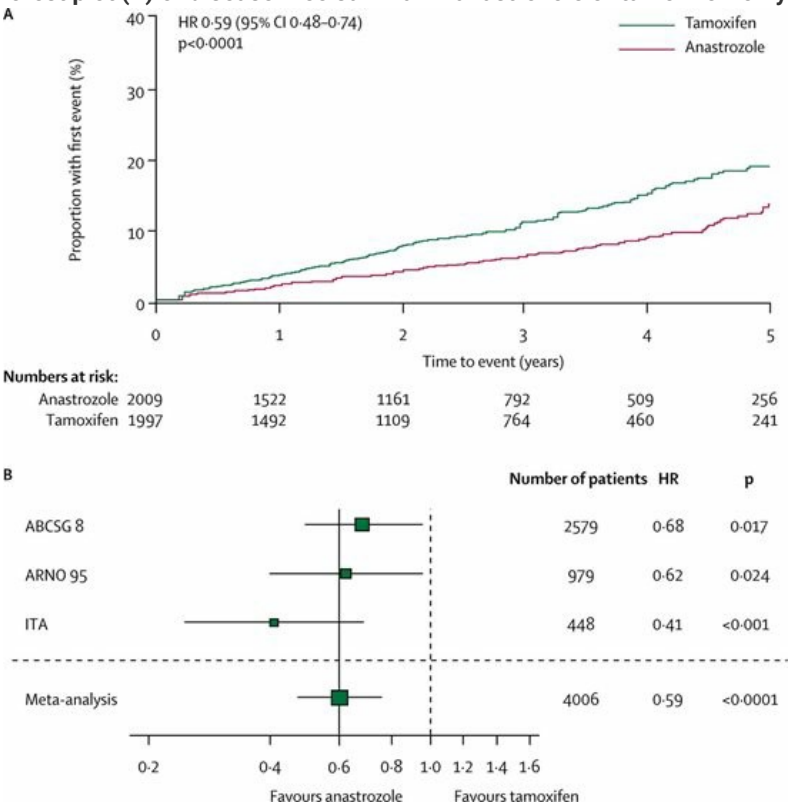
Postmenopausal women with histologically confirmed, hormone-sensitive early-stage breast cancer were randomised to either anastrozole 1 mg daily (n=2009) after 2 to 3 years of tamoxifen treatment or to continue with tamoxifen 20 or 30 mg daily (n=1997).

Median follow-up for the meta-analysis was 30 months (0–89.5), with a total duration of follow-up of 5389 person-years for the anastrozole group and 5339 person-years for the tamoxifen group. The results of this meta-analysis support the switch to anastrozole after 2 to 3 years of tamoxifen in this group of patients.

Efficacy

Patients who switched to anastrozole had fewer disease recurrences (92 vs 159) and deaths (66 vs 90) than did those who remained on tamoxifen, resulting in significant improvements in disease-free survival (HR 0.59, 95% CI 0.48 - 0.74; *p* <0.0001), event-free survival (0.55, 95% CI 0.42 - 0.71; *p* <0.0001), distant recurrence-free survival (0.61, 95% CI 0.45 - 0.83; *p* =0.002), and overall survival (0.71, 95% CI 0.52 - 0.98; *p* =0.04).

Kaplan-Meier curve (A) and forest plot (B) of disease-free survival in anastrozole or tamoxifen-only groups [7]



Toxicity

There were significantly more fractures (*p* =0.015) and significantly fewer thromboses (*p* =0.034) in patients treated with anastrozole than in those with tamoxifen. There was a trend towards fewer emboli and endometrial cancers with anastrozole. There was significantly more nausea and a trend towards more bone pain in the anastrozole group.[8]

Adverse events[8]

	Tamoxifen (n=1597)	Anastrozole (n=1602)	OR (95% CI), p
Myocardial infarction	2 (<1%)	3 (<1%)	1·50 (0·17–17·9), 1·0
Embolism	9 (<1%)	2 (<1%)	0·22 (0·02–1·07), 0·064
Thromboses	12 (<1%)	3 (<1%)	0·25 (0·04–0·92), 0·034
Fractures	16 (1%)	34 (2%)	2·14 (1·14–4·17), 0·015
Endometrial cancer	7 (<1%)	1 (<1%)	1·14 (0·003–1·11), 0·069

Adverse events[8]

	Tamoxifen (n=1117)	Anastrozole (n=1120)	OR (95% CI), p
Hot flushes	560 (50%)	537 (48%)	0·92 (0·77–1·09), 0·3209
Asthenia, somnolence	29 (3%)	37 (3%)	1·28 (0·76–2·18), 0·3880
Allergy, cutaneous toxicity, skin rash	16 (1%)	26 (2%)	1·63 (0·84–3·28), 0·1628
Hair loss	24 (2%)	35 (3%)	1·47 (0·84–2·60), 0·1901
Diarrhoea	9 (<1%)	15 (1%)	1·67 (0·68–4·35), 0·3080
Nausea	10 (<1%)	25 (2%)	2·53 (1·17–5·92), 0·0162
Vaginal bleeding/discharge	195 (17%)	198 (18%)	1·02 (0·81–1·27), 0·9348
Bone pain	177 (16%)	213 (19%)	1·25 (1·00–1·56), 0·0546

Cardiovascular, cerebrovascular and thromboembolic events for aromatase inhibitors compared to tamoxifen[6]

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Note: Significant differences are shown in bold face.
Abbreviations: →, followed by; A, anastrozole; ABCSG, Austrian Breast and Colorectal Cancer Study Group; ARNO, Arimadex/Nolvadex; ATAC, Arimidex , Tamoxifen, Alone or in Combination; BIG, Breast International Group; CABG, coronary artery bypass graft; CI, confidence interval; E, exemestane; IES, Intergroup Exemestane Study; ITA, Italian Tamoxifen Anastrozole; L, letrozole; NR, not reported; OR, odds ratio; PTCA, Percutaneous Transluminal Coronary Angioplasty; T, tamoxifen; TIA, Transient Ischemic Attack; Trmt, treatment; vs, versus.
[a] Favours anastrozole.

Evidence - Extended adjuvant therapy

The evidence regarding extended adjuvant therapy with anastrozole 1 mg daily is provided by the ABCSG-16/SALSA trial, which compared the addition of 2 vs 5 years of anastrozole in postmenopausal women with hormone receptor positive breast cancer who had already received 5 years of initial adjuvant endocrine therapy (with tamoxifen and/or an aromatase inhibitor).[2]

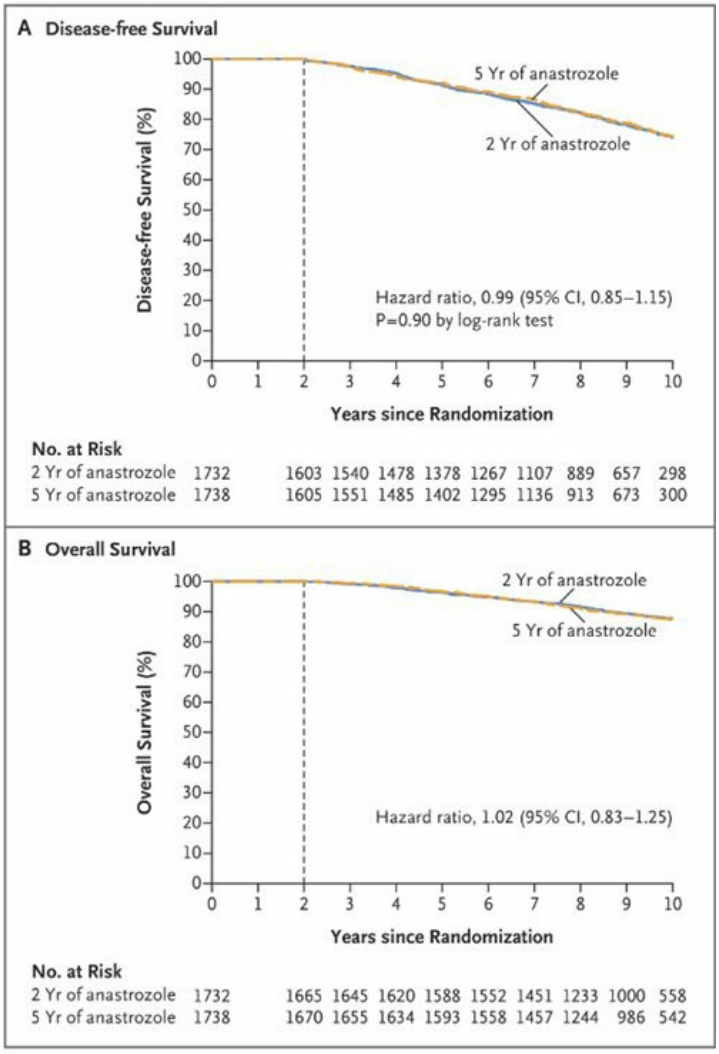
The primary analysis included 3208 patients who were recurrence free at 2 years after randomisation. The primary end point was disease free survival (DFS) and secondary end points included overall survival (OS), contralateral breast cancer, second primary cancer, and clinical bone fracture.

A review by van Hellemond et al suggests considering extended adjuvant endocrine therapy with aromatase inhibitors for a total of 5 to 10 years treatment only in women with high-risk early breast cancer who tolerate treatment well.[1]

Efficacy

The median follow up after randomisation was 118 months. DFS at 10 years post randomisation was 73.6% in the 2 year extended treatment group vs 73.9% in the 5 year extended treatment group (HR = 0.99, 95% CI, 0.85 to 1.15; P=0.90). OS was 87.5% and 87.3% respectively (HR = 1.02, 95% CI, 0.83 to 1.25).[2]

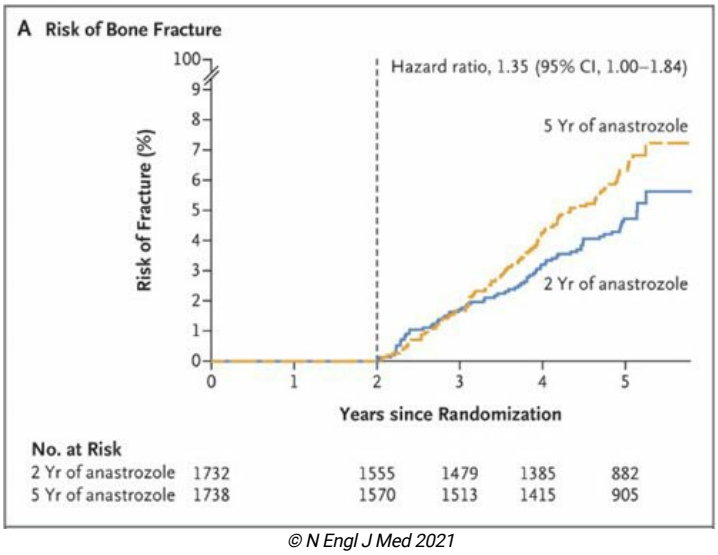
Kaplan Meier curves of (A) DFS and (B) OS[2]



Toxicity

The risk of clinical bone fracture at 5 years after randomisation was 4.7% in the 2 year group vs 6.3% in the 5 year group (HR = 1.35; 95% CI, 1.00 to 1.84).[2]

Kaplan Meier curve of bone fracture risk[2]



References

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2 Gnant, M., F. Fitzal, G. Rinnerthaler, et al. 2021. "Duration of Adjuvant Aromatase-Inhibitor Therapy in Postmenopausal Breast Cancer." N Engl J Med 385(5):395-405.

3 Baum, M., A. U. Budzar, J. Cuzick, et al. 2002. "Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: first results of the ATAC randomised trial." Lancet 359(9324):2131-2139.

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6 Eisen, A., M. Trudeau, W. Shelley, et al. 2008. "Aromatase inhibitors in adjuvant therapy for hormone receptor positive breast cancer: a systematic review." Cancer Treat Rev 34(2):157-174.

7 Jonat, W., M. Gnant, F. Boccardo, et al. 2006. "Effectiveness of switching from adjuvant tamoxifen to anastrozole in postmenopausal women with hormone-sensitive early-stage breast cancer: a meta-analysis." Lancet Oncol 7(12):991-996.

8 Jakesz, R., W. Jonat, M. Gnant, et al. 2005. "Switching of postmenopausal women with endocrine-responsive early breast cancer to anastrozole after 2 years' adjuvant tamoxifen: combined results of ABCSG trial 8 and ARNO 95 trial." Lancet. 366(9484):455-462.

History

Version 5

Date	Summary of changes
30/08/2022	Protocol reviewed at Medical Oncology reference committee meeting. Early switch information from ID 20 Breast adjuvant anastrozole (early switch) added to evidence section. Evidence updated with extended adjuvant therapy information. Clinical information oestrogen preparations updated to include topical oestrogen therapies. Clinical information vaccinations block removed. Version number changed to V.5. Next review in 4 years.

Version 4

Date	Summary of changes
12/10/2020	Protocol reviewed electronically by Medical Oncology Reference Committee. Treatment duration changed to a total of 5 to 10 years in treatment schedule, indications and patient information. Version number changed to V.4. Next review in 5 years.

Version 3

Date	Summary of changes
01/08/2009	Review and transferred to eviQ
17/01/2011	New format to allow for export of protocol information. Protocol version number changed to *V.2.* Antiemetics and premedications added to the treatment schedule. Additional Clinical Information, Key Prescribing table and Key Administration table combined into new section titled Clinical Considerations. Drug specific information placed behind the drug name link.
27/04/2012	Protocol reviewed at Medical Oncology Reference Committee meeting.

Date	Summary of changes
	Next review in 1 year.
21/04/2013	PBS restrictions updated.
20/06/2013	Evidence updated.
30/06/2013	Protocol reviewed by committee via email survey. No changes and next review in 2 years.
22/06/2015	Protocol reviewed electronically by Medical Oncology Reference committee. No changes and next review in 2 years.
18/02/2016	Discussion with Medical Oncology Reference Committee Chairs and protocol to be reviewed every 5 years. Next review due in 4 years.
31/05/2017	Transferred to new eviQ website. Version number change to V.3.

As ID 19 Breast adjuvant anastrozole replaces an existing approved protocol, the individual History section is included below for consistency in documentation.

ID 20 Breast adjuvant anastrozole (early switch) version 4	
Date	**Summary of changes**
11/01/2010	Review, new dose modifications and transferred to eviQ
05/05/2010	Link to Patient Information - "Managing Oral Cancer Treatments at Home" removed as chemotherapy safe handling is inappropriate for this treatment.
17/01/2011	New format to allow for export of protocol information. Protocol version number changed to *V.2.* Antiemetics and premedications added to the treatment schedule. Additional Clinical Information, Key Prescribing table and Key Administration table combined into new section titled Clinical Considerations. Drug specific information placed behind the drug name link.
27/04/2012	Protocol reviewed at Medical Oncology Reference Committee meeting. No changes and next review in 1 year.
21/04/2013	PBS restrictions updated.
30/06/2013	Protocol reviewed by committee via email survey. No changes and next review in 2 years.
22/06/2015	Protocol reviewed electronically by Medical Oncology Reference committee. No changes and next review in 2 years.
18/02/2016	Discussion with Medical Oncology Reference Committee Chairs and protocol to be reviewed every 5 years. Next review due in 4 years.
31/05/2017	Transferred to new eviQ website. Version number change to V.3.
09/10/2019	Duration updated in treatment schedule, indications and patient information. Version number changed to V.4.
12/10/2020	Protocol reviewed electronically by Medical Oncology Reference Committee. Reference added in indications section. Next review in 5 years.

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Patient information - Breast cancer adjuvant - Anastrozole

Patient's name:

Your treatment

It is important to understand that anastrozole is not a traditional chemotherapy drug and has a different way of working. It works by reducing hormones which stops the cancer cells growing and spreading. The treatment schedule below explains how the drug for this treatment is given.

Anastrozole

This treatment is continuous. Hormonal treatment is given for 5 to 10 years in total. Your doctor will advise you how long to take the treatment for. Do not stop taking anastrozole tablets without telling your doctor.

Day	Treatment	How it is given
Continuous	**Anastrozole** *(an-as-troe-zole)*	Take orally ONCE a day at the same time each day. Can be taken with or without food. If you forget to take a tablet or vomit a tablet, take your normal dose the next time it is due. Do not take an extra dose.

When to get help

Anticancer drugs (drugs used to treat cancer) can sometimes cause serious problems. It is important to get medical help immediately if you suddenly become unwell.

IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse if you notice any pain or swelling in your legs or arms or if you develop any sudden shortness of breath or chest pain

Emergency contact details

Ask your doctor or nurse from your treating team who to contact if you have a problem

Daytime: .....

Night/weekend: .....

Other instructions: .....

.....

.....

.....

Other information about your treatment

Treatment delays

There may be times when your treatment is delayed. This can happen if your doctor thinks you are likely to have severe side effects, if you get severe side effects, if your blood counts are affected and causing delays in treatment, or if you are finding it hard to cope

with the treatment. Your doctor will explain if you need any delays to your treatment and the reason why.

Blood tests and monitoring

You may need to have blood tests while you are receiving this treatment. Your doctor or nurse will tell you when to have these blood tests.

Hormonal cancer treatment

Certain types of breast cancer need oestrogen to grow. Anastrozole works by reducing the supply of oestrogen to these cancer cells.
You may notice some vaginal bleeding in the first few weeks of treatment. If the bleeding continues tell your doctor or nurse. Some people may experience hair thinning with this treatment. This is usually mild and rarely results in significant hair loss.
You must not take any medications that contain oestrogen while you are having treatment with anastrozole. This includes some oral contraceptives, hormone replacement therapy (HRT) and oestrogen creams. Ask your doctor or pharmacist for more information.

Other medications given during this treatment

- **Calcium and vitamin D supplements:** you may be given some calcium and vitamin D tablets. Your doctor or nurse will tell you how and when to take these.

Side effects

Cancer treatments can cause damage to normal cells in your body, which can cause side effects. Everyone gets different side effects, and some people will have more problems than others.

The table below shows some of the side effects you may get with this treatment. You are unlikely to get all of those listed and you may also get some side effects that have not been listed.

Tell your doctor or nurse about any side effects that worry you. Follow the instructions below and those given to you by your doctor or nurse.

Immediate (onset hours to days)	
Headache	• You can take paracetamol if you have a headache. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get a very bad headache that is not helped by pain medication.**
Nausea and vomiting	• You may feel sick (nausea) or be sick (vomit). • Drink plenty of fluids (unless you are fluid restricted). • Eat small meals more frequently. • Try food that does not require much preparation. • Try bland foods like dry biscuits or toast. • Gentle exercise may help with nausea. • Anti-sickness medication is usually not needed but may help in some people. • Ask your doctor or nurse for eviQ patient information - Nausea and vomiting during cancer treatment. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have uncontrolled vomiting or feel dizzy or light-headed.**

Early (onset days to weeks)	
Hot flushes	• You may get flushing of your face, sweating and sensations of heat. • Avoid alcohol, coffee, tea and spicy foods, as they can make hot flushes worse. • Wear lightweight clothes made from natural fibres; dress in layers. • Put a cold, wet towel against your neck during hot flushes. • Talk to your doctor or nurse about other ways to manage these symptoms.
High blood cholesterol levels	• This treatment may increase your blood cholesterol levels. This is not a side effect you will notice. • Your cholesterol levels will be checked during your treatment.
Extra fluid in the body (fluid retention)	• You may gain weight over a short amount of time. • Your hands and feet may become swollen, appear red or feel hot and uncomfortable. • Wear loose clothing and shoes that are not too tight. • Try not to stand up or walk around too much at one time. • If your ankles or legs get swollen, try raising them. • Make sure that any cuts or areas of broken skin are treated as soon as possible. • **Tell your doctor or nurse as soon as possible if you get any of the symptoms listed above or gain 1 to 2 kg in a week.** • **Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you become short of breath.**

Late (onset weeks to months)	
Joint and muscle pain and stiffness	• You may get muscle, joint or general body pain and stiffness. • Applying a heat pack to affected areas may help. • Talk to your doctor or nurse about other ways to manage these symptoms. You may need medication to help with any pain.
Vaginal changes	• You may get a dry vagina. • This may cause pain or discomfort during sex. • Use a vaginal moisturiser. • Before sex use a water-based lubricating gel. • Talk to your doctor or nurse about other ways to manage these symptoms.

Delayed (onset months to years)	
Weak and brittle bones (osteoporosis)	• Your bones may fracture easily and may become painful. • You may have trouble moving around. • You may find it hard to perform daily chores. • Try to do some weight-bearing exercise for 30 minutes at least three times a week. • Watch out for slippery floors and make sure walkways are well lit. • Take calcium and vitamin D supplements if prescribed by your doctor. • You may have regular tests to check your bones both before and during treatment. • Tell your doctor or nurse if you get any of the signs or symptoms listed above.

General advice for people having cancer treatment

Blood clot risk

- Cancer and anticancer drugs can increase the risk of a blood clot (thrombosis).
- Tell your doctor if you have a family history of blood clots.
- A blood clot can cause pain, redness, swelling in your arms or legs, shortness of breath or chest pain.
- If you have any of these symptoms go to your nearest hospital Emergency Department.

Medications and vaccinations

- Before you start treatment, tell your doctor about any medications you are taking, including vitamins or herbal supplements.
- Don't stop or start any medications during treatment without talking to your doctor and pharmacist first.
- Vaccinations such as flu and tetanus vaccines are safe to receive while you are having treatment. If you are unsure, check with your doctor before you have any vaccinations.

Other medical and dental treatment

- If you go to hospital or any other medical appointment (including dental appointments), always tell the person treating you that you are receiving anticancer drugs.
- Before you have any dental treatment, talk to your doctor.

Diet

- While you are receiving this treatment it is important that you try to maintain a healthy diet.
- Speak to your doctor or nurse about whether drinking alcohol is safe with your treatment.
- If you have any concerns about recent weight loss or weight gain or questions about your diet, ask to speak to a dietitian.

Sex life and sexuality

- The desire to have sex may decrease as a result of this treatment or its side effects.
- Your emotions and the way you feel about yourself may also be affected by this treatment.
- It may help to discuss your concerns with your partner and doctor or nurse.

Quitting smoking

- It is never too late to quit smoking. Quitting smoking is one of the best things you can do to help your treatment work better.
- There are many effective tools to improve your chances of quitting.
- Talk to your treating team for more information and referral to a smoking cessation support service.

Staying active

- Research shows that exercise, no matter how small, has many benefits for people during and after cancer treatment.
- Talk to your doctor before starting an exercise program. Your doctor can advise whether you need a modified exercise program.

For more information about cancer treatment, side effects and side effect management see our Patient and carers section.

Where to get more information

Telephone support

- Call Cancer Council on 13 11 20 for cancer information and support.

Breast cancer information

- Australasian Lymphology Association – lymphoedema.org.au
- Australasian Menopause Society – menopause.org.au
- Breast Cancer Network Australia – bcna.org.au
- National Breast Cancer Foundation – nbcf.org.au
- YWCA Encore breast cancer exercise program – ywcaencore.org.au

General cancer information and support

- Australian Rare Cancer (ARC) Portal – arcportal.org.au/
- Beyondblue – beyondblue.org.au
- Cancer Australia – canceraustralia.gov.au
- Cancer Council Australia – cancer.org.au
- Cancer Voices Australia – cancervoicesaustralia.org
- CanTeen – canteen.org.au
- Carers Australia – carersaustralia.com.au
- CHILL Cancer related hair loss – scalpcooling.org
- eviQ Cancer Treatments Online – eviQ.org.au
- LGBTQI+ People and Cancer - cancercouncil.com.au/cancer-information/lgbtqi
- Look Good Feel Better – lgfb.org.au

- Patient Information – patients.cancer.nsw.gov.au
- Radiation Oncology Targeting Cancer – targetingcancer.com.au
- Redkite – redkite.org.au
- Return Unwanted Medicines – returnmed.com.au
- Staying active during cancer treatment – patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/staying-active

Quit smoking information and support

Quitting smoking is helpful even after you have been diagnosed with cancer. The following resources provide useful information and support to help you quit smoking. Talk to your treating team about any other questions you may have.

- Call Quitline on 13 QUIT (13 78 48)
- iCanQuit – iCanQuit.com.au
- Patient Information – patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/quitting-smoking
- Quitnow – quitnow.gov.au

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