Trial record **1 of 1** for: 9238SW/0001
Previous Study | Return to List | Next Study

Anastrozole Monotherapy Versus Maximal Oestrogen Blockade With Anastrozole and Fulvestrant Combination Therapy (FACT)

This study has been completed.

Sponsor:
AstraZeneca

Information provided by (Responsible Party):
AstraZeneca

ClinicalTrials.gov Identifier:
NCT00256698

First received: November 20, 2005
Last updated: July 27, 2012
Last verified: July 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Tracking Information	
First Received Date ICMJE	November 20, 2005
Last Updated Date	July 27, 2012
Start Date ICMJE	January 2004
Primary Completion Date	April 2009 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: January 12, 2011)**	Time to Progression (TTP) [Time Frame: RECIST assessments carried out every 8 weeks from randomisation until data cut-off on 30th April 2009] [Designated as safety issue: No] RECIST (Response Evaluation Criteria in Solid Tumours) assessments carried out every 8 weeks from randomisation until data cut-off on 30th April 2009. TTP, time in months to worsen 'progression' according to RECIST criteria. (RECIST is a set of published rules that define when cancer patients improve "respond", stay the same "stable"or worsen "progression" during treatments.
Original Primary Outcome Measures ICMJE **(submitted: November 20, 2005)**	Time to progression
Change History	Complete list of historical versions of study NCT00256698 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: January 12, 2011)**	• Percentage of Evaluable Participants With Objective Response Rate (ORR) [Time Frame: RECIST tumour assessments carried out every 8 weeks from randomisation until data cut-off on 30th April 2009] [Designated as safety issue: No] No. of patients who were objective responders over the no. of patients evaluable for response x100. An objective responder = a patient whose best response is either CR (disappearance of all lesions) or PR (>= 30% shrinkage in the sum of the longest diamemeters of the measurable lesions + no new lesions + no progression of non-measurable lesions) • Percentage of Clinical Benefit Rate (CBR) Responders [Time Frame: RECIST tumour assessments carried out every 8 weeks from randomisation until data cut-off on 30th April 2009] [Designated as safety issue: No] No. of patients who were clinical benefit responders over the no. of randomised patients x100. A clinical benefit responder = a patient whose best response is CR, PR or SD>=24 weeks (where a best response of SD = no new lesions and for existing lesions; neither suffient shrinkage to count as PR nor sufficient growth to count as progression) • Duration of Response (DoR) [Time Frame: RECIST tumour assessments carried out every 8 weeks from randomisation until data cut-off on 30th April 2009] [Designated as safety issue: No] Median time from randomisation until objective progression or death (in the absence of objective progression), measured only in those patients who are objective responders • Duration of Clinical Benefit (DoCB) [Time Frame: RECIST tumour assessments carried out every 8 weeks from randomisation until data cut-off on 30th April 2009] [Designated as safety issue: No] Median time from randomisation until objective progression or death (in the absence of objective progression), measured only in those patients who are clinical benefit responders

	• Time to Treatment Failure (TTF) [Time Frame: From randomisation until data cut-off on 30th April 2009] [Designated as safety issue: No] Time from randomisation until the date of discontinuation of randomised treatment for any reason • Overall Survival (OS) [Time Frame: All deaths occurring between randomisation and data cut-off on 30th April 2009 are included.] [Designated as safety issue: No] Overall survival is equivalent to time to death. Time from randomisation until the date of death
Original Secondary Outcome Measures ICMJE **(submitted: November 20, 2005)**	• Objective tumour response • clinical benefit, safety
Current Other Outcome Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	Anastrozole Monotherapy Versus Maximal Oestrogen Blockade With Anastrozole and Fulvestrant Combination Therapy
Official Title ICMJE	FACT: Anastrozole Monotherapy Versus Maximal Oestrogen Blockade With Anastrozole and Fulvestrant Combination Therapy; an Open Randomized, Comparative, Phase III Multicentre Study in Postmenopausal Women With Hormone Receptor Positive Breast Cancer in First Relapse After Primary Treatment of Localized Tumor.
Brief Summary	The purpose of this study is to determine the efficacy of anastrozole monotherapy versus maximal oestrogen blockade with combinated therapy of fulvestrant and anastrozole compared with in treatment of hormone receptor positive women with first relapse of breast cancer.
Detailed Description	*Not Provided*
Study Type ICMJE	Interventional
Study Phase	Phase 3
Study Design ICMJE	Allocation: Randomized Endpoint Classification: Efficacy Study Intervention Model: Parallel Assignment Masking: Open Label Primary Purpose: Treatment
Condition ICMJE	Breast Cancer
Intervention ICMJE	• Drug: Fulvestrant intramuscular injection 250 mg loading dose (LD) regimen Other Names: ◦ Faslodex ◦ ZD9238 • Drug: Anastrozole 1 mg oral tablet Other Names: ◦ Arimidex ◦ ZD1033
Study Arm (s)	• Active Comparator: 1 Anastrozole Intervention: Drug: Anastrozole • Experimental: 2 Anastrozole + Fulvestrant Interventions: ◦ Drug: Fulvestrant ◦ Drug: Anastrozole
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information	
Recruitment Status ICMJE	Completed
Enrollment ICMJE	514
Completion Date	February 2012
Primary Completion Date	April 2009 (final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: • Signed informed consent, postmenopausal females, histological or cytological confirmed oestrogene and/or progesterone (PgR) receptor positive breast cancer, local recurrence or metastasis Exclusion Criteria: • Previous systemic endocrine therapy for advanced or recurrent disease; prior fulvestrant therapy • Premenopausal women
Gender	Female
Ages	Child, Adult, Senior
Accepts Healthy Volunteers	No
Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Listed Location Countries ICMJE	Canada, Costa Rica, Finland, France, Germany, Guatemala, Iceland, Italy, Norway, Portugal, Sweden, Turkey
Removed Location Countries	

Administrative Information	
NCT Number ICMJE	NCT00256698
Other Study ID Numbers ICMJE	D6997L00002, **9238SW/0001**, FACT
Has Data Monitoring Committee	*Not Provided*
Plan to Share Data	*Not Provided*
IPD Description	*Not Provided*
Responsible Party	AstraZeneca
Study Sponsor ICMJE	AstraZeneca
Collaborators ICMJE	*Not Provided*
Investigators ICMJE	Study Director: Roger Henriksson, MD AstraZeneca
Information Provided By	AstraZeneca
Verification Date	July 2012

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**