

# Use of non steroidal aromatase inhibitors in treatment of patients with early invasive hormone-dependent breast cancer in everyday clinical practice

<b>Submission date</b> 26/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/06/2011	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Eduard Vrdoljak

### Contact details

Clinical Hospital Center Split  
Split  
Croatia  
21000

## Additional identifiers

### Protocol serial number

ANA-2010/01-HR

## Study information

### Scientific Title

Use of non steroidal aromatase inhibitors in treatment of patients with early invasive hormone-dependent breast cancer in everyday clinical practice: non-interventional, multicentre study

**Study objectives**

The main aim is to assess patients compliance to non steroidal aromatase inhibitors. The patients will be considered compliant if they take > 80% of medication. According to published data it is expected that patients who have been receiving aromatase inhibitors (AI) therapy for longer period of time (i.e. for 3 years at the beginning of this non-interventional study) will be less compliant than those who have been started with the therapy recently. In addition it is expected that approximately 20% of all included patients will be non-compliant which allows us to analyse influence of socioeconomic parameters on non-compliance (which is one of our secondary objectives).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Central Ethics Committee, Croatia approved on 23rd March 2011

**Study design**

Non-interventional multicentre study

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Early invasive hormone-dependent breast cancer

**Interventions**

Patients on non steroidal aromatase inhibitors will come for 6 visits: baseline, after 2, 6, 12, 18 and 24 months - which reflects standard practice in Croatia. Only clinical examination and those diagnostic methods which are part of standard clinical practice in Croatia will be performed. Investigators will record in patients case report form (CRF) which methods have been performed at each visit. In case of disease progression, patient will end the study.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Non steroidal aromatase inhibitors

**Primary outcome(s)**

Patients' compliance to non steroidal aromatase inhibitors therapy in everyday clinical practice in Croatia. Patient will be given diary in which she will assess how many doses she has missed each month. This will be checked by the Investigator at each visit. In addition, if patients is not taking the medication regularly, the Investigator will record the reason [i.e. adverse drug reactions (ADR), forgetting to take medication, etc]

**Key secondary outcome(s)**

1. Patients compliance to therapy for prevention and/or treatment of osteoporosis (if any prescribed)
2. Influence of socioeconomic parameters on patients compliance
3. Effectiveness of non-steroidal inhibitors in everyday clinical practice in Croatia (progression free survival, time to progression, overall survival)
4. Safety of non steroidal aromatase inhibitors

**Completion date**

31/12/2013

**Eligibility****Key inclusion criteria**

1. Patients with early invasive breast cancer
2. Hormone-dependent disease
3. Postmenopausal women
4. Eastern Cooperative Oncology Group (ECOG) 0-1
5. Signed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Metastatic breast cancer
2. Premenopausal women
3. Pregnancy or lactation
4. Patients with severe renal impairment
5. Patients with moderate to severe hepatic disease
6. Known hypersensitivity to anastrozole or letrozole or any of the excipients
7. Concurrent oestrogen containing therapy
8. Concurrent tamoxifen therapy
9. Previous treatment with tamoxifen
10. Previous treatment with any other aromatase inhibitor

**Date of first enrolment**

27/04/2011

**Date of final enrolment**

31/12/2013

# Locations

## Countries of recruitment

Croatia

## Study participating centre

Clinical Hospital Center Split

Split

Croatia

21000

# Sponsor information

## Organisation

PLIVA Croatia Ltd. (Croatia)

## ROR

<https://ror.org/02ctha95>

# Funder(s)

## Funder type

Industry

## Funder Name

PLIVA Croatia Ltd. (Croatia)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes