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

Submission date
26/04/2011

Recruitment status
No longer recruiting

Registration date
06/06/2011

Overall study status
Completed

Last Edited
06/06/2011

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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]

Secondary outcome measures
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 aromatse inhibitors

Overall study start date
27/04/2011

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

Age group
Adult

Sex
Female

Target number of participants
500

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)

Sponsor details
Prilaz baruna Filipovic 25
Zagreb
Croatia
10000

Sponsor type
Industry

ROR
https://ror.org/02cthxa95

Funder(s)

Funder type
Industry

Funder Name
PLIVA Croatia Ltd. (Croatia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration