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Evaluation of clinical benefits of abiraterone acetate in "real life" study

Submission date 30/04/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/05/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/02/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Prostate cancer is a very common cancer affecting men. The prostate is a small gland in the pelvis. It is found only in men and is usually the size of a satsuma. Its function is to help with the production of semen, producing a thick white fluid to be mixed with sperm. Cancer of the prostate usually develops slowly, so patients may not be aware that they have the disease for many years. In some cases, the cancer is only diagnosed at a later stage, when the disease has already spread (and called metastatic prostate cancer). Symptoms include needing to urinate more frequently than before, needing to rush to the toilet, having problems passing urine, and feeling that the bladder is not completely empty after urinating. In advanced cases, the cancer may spread to the bones and lymph nodes and, more rarely, the lungs and the liver. Treatment options include radiotherapy, hormone therapy, chemotherapy and partial or complete removal of the prostate. Testosterone usually makes the cancer grow more quickly so treatments can be given to stop the body producing so much of this hormone. In some cases, the part of the testicle that produces the testosterone is removed. After a time, these treatments can stop working, at which point the cancer is known as castration resistant prostate cancer. Studies have shown that a treatment called abiraterone acetate (AA) can improve survival for men with metastatic castration-resistant prostate cancer. This study aims to gain a better understanding regarding the use of this drug in clinical practice.

Who can participate?
Men diagnosed with metastatic prostate cancer, treated with AA.

What does the study involve?
Patients are treated with 1000mg of AA once a day and 5mg prednisone twice a day. This treatment continues until the disease progresses, the participant dies or the treatment becomes too toxic to take any more.

What are the possible benefits and risks of participating?
Participants may benefit from taking part in this study though receiving a comprehensive, tailored follow-up.

Where is the study run from?
At least nine prostate cancer treatment centers in Italy

When is study starting and how long is it expected to run for?
November 2015 to November 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Luca Cindolo

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Abiraterone acetate plus prednisone in chemotherapy-naive men with metastatic castration-resistant prostate cancer: multicentre Italian “real life” study

Study objectives
The aim of the study is to verify in clinical practice the results of RCTs concerning the abiraterone acetate in chemonaive patients wih metastatic castration-resistant prostate cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was waived by the departmental IRB.

Study design
Retrospective multicentre observational

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Metastatic castration resistant prostate cancer

Interventions
All patients enrolled were patients with an indication to receive abiraterone acetate (AA). All consecutive patients with biochemically or histologically confirmed progressive metastatic castration-resistant prostate cancer (mCRPC) and castrate levels of testosterone (<50 ng/dl.), chemonaive, treated with AA plus prednisone in 8 Italian tertiary cancer centres were gathered into a dedicated database. Patients were treated with AA 1000mg once daily in association with with prednisone 5mg twice a day until disease progression, death or unacceptable toxicity.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Abiraterone acetate

Primary outcome measure
Progression free survival of patients enrolled (Overall Survival (OS), defined as time from the first dose of AA to the first clinical (pain, general status) or radiographic event), assessed from the time between treatment initiation to either the date of death or of last follow-up for surviving patients.

Secondary outcome measures
1. PSA changes measured at the baseline and at 12 weeks (the PSA decline was defined as a response at 12 wk equal or greater than 50% in PSA relative to baseline)
2. Toxicity according to the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) 4.02 toxicity scale, assessed be evaluated monthly or earlier in case of toxic event
3. Dropout rate and the reasons for discontinuation, evaluated monthly or earlier in case of premature dropout
4. Patient's satisfaction about the treatment, using a 4-items specific questionnaire ("My condition has been: 1- greatly improved, 2- improved, 3- not changed, 4- worsened, during treatment"), evaluated every 12weeks or earlier in case of dropout

Overall study start date
01/08/2015

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. Men over the age of 18
2. Biochemically or histologically confirmed progressive mCRPC
3. Castrate levels of testosterone (<50 ng/dl)
4. Chemonaive
5. Eligible for abiraterone acetate

Participant type(s)
Patient

Age group
Senior

Lower age limit
18 Years

Sex
Male

Target number of participants
150

Total final enrolment
145

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment

01/11/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
Italy

Study participating centre
Urology Department
ASL Abruzzo 2
Chieti
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66100

Sponsor information

Organisation
Urology Department ASL Abruzzo 2

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
A brief report on progression free survival and on patient's satisfaction will be done in the summer of 2016; a complete paper with OS data and longer follow-up will be prepared in Winter 2016/2017.
An oral communication on these data was done during the National Congress of Italian Society of Urology , held in Venice in October 2016.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The dataset supporting the conclusions of this article is included as additional file to the results publication. The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/11/2017		Yes	No