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Open randomised study of previously untreated metastatic prostate cancer patients comparing intermittent to continuous treatment with cyproterone acetate: evaluation of step-up therapy adding an luteinising hormone releasing hormone agonist upon progression is included

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
20/08/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
A309904

Study information

Scientific Title
Open randomised study of previously untreated metastatic prostate cancer patients comparing intermittent to continuous treatment with cyproterone acetate: evaluation of step-up therapy adding an luteinising hormone releasing hormone agonist upon progression is included

Acronym
RSG-CPA study

Study objectives
Intermittent androgen deprivation using Cyproterone Acetate (CPA) oral monotherapy improves the overall quality of life while achieving similar control of tumour growth to that attained by continuous CPA treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate Cancer

Interventions
CPA 300 mg/day continuous versus CPA 300 mg/day intermittent

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cyproterone Acetate (CPA) oral monotherapy

Primary outcome(s)

1. Time to PSA progression after at least three months of continuous CPA
2. Time to clinical disease progression after at least three months of continuous CPA
3. Quality of life
4. The ratio and length of time without anti-androgenic treatment in the intermittent arm of the trial

Key secondary outcome(s))
1. Time to secondary PSA progression after castration
2. Time to clinical disease progression after castration
3. Time to disease specific mortality
4. Overall mortality (all causes)

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Histologically or cytologically proven prostate cancer
2. M1a, M1b or M1c, irrespective of T-stage or N-stage
3. Increased Prostate Specific Antigen (PSA) serum level: PSA greater than or equal to 20 ng/ml and PSA less than 1000 ng/ml
4. World Health Organisation (WHO) performance status zero, one or two
5. No specific treatment for prostate cancer except for radical prostatectomy, Transurethral Resection of the Prostate (TURP) or radical radiotherapy. Any neo-adjuvant treatment prior to curative treatment must have been completed more than six months before entering the study
6. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. N+ M0, patients with regional lymph node metastases only are excluded
2. Orchiectomy
3. Testosterone in the castration range at registration
4. Life expectancy of less than 12 months
5. Presence or history of other neoplasms, unless considered cured (no evidence or tumour or at least five years)
6. Presence of progressive fatal disease other than prostate cancer
7. Presence of liver diseases (Aspartate Aminotransferase [AST] or Alanine Aminotransferase

[ALT] higher than 25 times upper limit of normal)
8. Presence of sickle cell anaemia
9. Clinically relevant major systemic disease making implementation of the protocol or interpretation of the study results difficult
10. History of or presently known depressions or psychiatric disorders
11. Probable non-compliance to trial protocol
12. Hypersensitivity to CPA

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Schering AG (The Netherlands)

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?
Results article		21/11/2013	20/08/2021	Yes	No