Open randomized study of previously untreated metastatic prostate cancer patients comparing intermittent to continuous treatment with cyproterone acetate. Evaluation of step-up therapy adding an LHRH agonist upon progression is included.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21877

Source
Nationaal Trial Register

Brief title
RSG-CPA study

Health condition

Metastatic prostate cancer

Sponsors and support

Primary sponsor: Dept. Urology Erasmus MC
Source(s) of monetary or material Support: Schering AG

Intervention

Outcome measures

Primary outcome

1. Time to PSA progression after at least three months of continuous CPA and/or;

2. Time to clinical disease progression after at least three months of continuous CPA and;

3. Quality of life and;

4. The ratio and length of time without anti-androgenic treatment in the intermittent arm of the trial.

Secondary outcome

1. Time to secondary PSA progression after castration and/or;

2. Time to clinical disease progression after castration and;

3. Time to disease specific mortality;

4. Overall mortality (all causes).

Study description

Background summary

The primary aim of this study is to investigate whether intermittently administered CPA is superior to continuously administered CPA with respect to:

1. time to PSA progression after at least three months of continuous CPA and/or

2. time to clinical disease progression after at least three months of continuous CPA and

3. quality of life and

4. the ratio and length of time without anti-androgenic treatment in the intermittent arm of the trial.

Secondary endpoints are:

1. time to secondary PSA progression after castration and/or

2. time to clinical disease progression after castration and

3. time to disease specific mortality

4. overall mortality (all causes).

The study is an open-label, multi-centre trial, taking place in several European countries. Before being assigned to either treatment group, the patients will receive continuous oral CPA treatment of 300 mg/day in a preliminary phase (pre-phase) lasting 3-6 months, depending on their PSA response. After the pre-phase, an evaluation of hormone sensitivity will be done and patients will be stratified in good, moderate and non-responders. Non responders (stable PSA or PSA increase in the pre-phase) are withdrawn from the study.

Study objective

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

Intervention

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

Contacts

Public
Erasmus Medical Center,
P.O. Box 2040
M.F. Wildhagen
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4634191
Scientific
Erasmus Medical Center,
P.O. Box 2040
M.F. Wildhagen
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4634191

Eligibility criteria

Inclusion criteria

1. Histologically or cytologically proven prostate cancer;

2. M1a, M1b or M1c, irrespective of T-stage or N-stage;

3. Increased PSA serum level: PSA ³ 20 ng/ml and PSA £ 1000 ng/ml;

4. WHO performance status 0, 1 or 2;

5. No specific treatment for prostate cancer except for radical prostatectomy, TURp or radical radiotherapy.
Any neo-adjuvant treatment prior to curative treatment must have been completed more than 6 months before entering the study;

6. Signed informed consent.

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 (AST or ALT higher than 2.5 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2000
Enrollment:	800
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL99
NTR-old	NTR130
Other	: A309904
ISRCTN	ISRCTN11311736

Study results

Summary results
N/A