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.

Gepubliceerd: 23-08-2005 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21877

Bron
NTR

Verkorte titel
RSG-CPA study

Aandoening

Metastatic prostate cancer

Ondersteuning

Primaire sponsor: Dept. Urology Erasmus MC
Overige ondersteuning: Schering AG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 Non responders (stable PSA or PSA increase in the pre-phase) are withdrawn from the study.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2000
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A