Neoadjuvant pre-radical prostatectomy gene therapy (HSV-tk gene transduction followed by Ganciclovir) in patients with poor prognostic indicators.

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

N/A

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

Samenvatting

ID

NL-OMON21955

Bron
Nationaal Trial Register

Verkorte titel
Genetherapy 1

Aandoening

Localised prostate cancer

Ondersteuning

Overige ondersteuning: Erasmus MC Revolving Fund

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To study the safety and toxicity of adenovirus-mediated thymidine kinase gene therapy for

the neoadjuvant treatment of prostate cancer. This is established by patient monitoring from day 0 to day 14, during hospitalization for surgery (day 21 till 28), and subsequently during routine follow-up at weeks 6 and 12, months 6, 9 and 12 and every 6 months thereafter. For this purpose, PSA, blood count, serum hepatic enzumes and creatinine measurements are performed according to routine clinical procedures. A clinical follow-up of one year will be used for safety and toxicity analysis.

Toelichting onderzoek

Achtergrond van het onderzoek

This Phase I dose-escalating study is designed to analyse the safety and effects of adenovirus-mediated thymidine kinase gene transfection into prostate cells, followed by systemic Ganciclovir treatment in patients with poor risk confined prostate carcinoma. Three weeks after gene therapt radical prostatectomy will be performed, enabling the evaluation of the histological effects.

Doel van het onderzoek

N/A

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Intratumoral gene therapy with adenoviral vector coding for HSV-tk followed by Ganciclovir treatment.
Patients are treated with gene therapy three weeks prior to radical prostatectomy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Man, 35-70 years old;

2. Histologically proven adenocarcinoma of the prostate which is clinically localized (including bone scan, not CT);

3. PSA > 4 ng/ml;

4. Medically fit;

5. Scheduled to undergo radical prostatectomy;

6. Neutrophils ³ 2 x 109 /L , platelets ³ 100 x 109 /L, bilirubin < 40 ng/l, ASAT, ASAT < 4 x normal, Hb ³ 6.5 mmol/l, Creatinin < 150 ng/l, normal thromboplastin time (PTT) and prothrombin time (PT);

7. Living within one hour travel distance of the hospital;

8. Written consent for gene therapy after appropriate information.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior androgen ablation hormonal therapy (except treatment with finasteride – If discontinued > 3 months prior to inclusion);

2. Prior surgery or other invasive treatment for BPH (i.e. TURp, hyperthermia, laser prostatectomy, etc);

3. Patients on corticosteroids;

4. Concurrent treatment with immunosuppessive drugs (Imuran, cyclophosphamide etc);

5. Uncontrolled infections (defined as viral, bacterial of fungal infections requiring specific therapy);

6. HIV positive patients;

7. Immunocompromised patients.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-02-2001
Aantal proefpersonen:	12
Type:	Werkelijke 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	NL98
NTR-old	NTR129
Ander register	: A300009
ISRCTN	ISRCTN21565532

Resultaten

Samenvatting resultaten

1. van der Linden RRM, Haagmans BL, Mongiat-Artus P, van Doornum GJ, Kraaij R, Kadmon D, Aguilar-Cordova E, Osterhaus ADME, van der Kwast TH and Bangma CH. Virus specific immune responses after human neoadjuvant adenovirus-mediated suicide gene therapy for prostate cancer. European Urology 2005;48:153-61.