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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21955

Source
Nationaal Trial Register

Brief title
Genetherapy 1

Health condition

Localised prostate cancer

Sponsors and support

Source(s) of monetary or material Support: Erasmus MC Revolving Fund

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To study and characterize the biological effects of and the immune response induced by adenovirus-mediated thymidine kinase gene therapy.

Study description

Background summary

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.

Study objective

N/A

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2001
Enrollment:	12
Type:	Actual

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	NL98
NTR-old	NTR129
Other	: A300009
ISRCTN	ISRCTN21565532

Study results

Summary results

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.