

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/10/2007	Condition category Cancer	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

A300009

Study information

Scientific Title

Acronym

Genetherapy 1

Study objectives

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 therapy, radical prostatectomy will be performed, enabling the evaluation of the histological effects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Phase I, non-randomised, non-controlled, dose-escalating study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Intratatumoral 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.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

HSV-tk gene transduction, Ganciclovir

Primary outcome measure

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 hospitalisation for surgery (day 21 - 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 enzymes 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 measures

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

Overall study start date

20/02/2001

Completion date

01/09/2007

Eligibility**Key inclusion criteria**

1. Men, 35 - 70 years old
2. Histologically proven adenocarcinoma of the prostate which is clinically localised (including bone scan, not Computed Tomography [CT])
3. Prostate Specific Antigen (PSA) greater than 4 ng/ml
4. Medically fit
5. Scheduled to undergo radical prostatectomy
6. Neutrophils = $2 \times 10^9/l$, platelets = $100 \times 10^9/l$, bilirubin less than 40 ng/l, Aspartate Aminotransferase (ASAT) less than 4 x normal, Haemoglobin (Hb) = 6.5 mmol/l, Creatinine less than 150 ng/l, Partial 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

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

12

Key exclusion criteria

1. Prior androgen ablation hormonal therapy (except treatment with finasteride if discontinued greater than 3 months prior to inclusion)
2. Prior surgery or other invasive treatment for Benign Prostatic Hyperplasia (BPH) (i.e. Transurethral Resection of the Prostate [TURP], hyperthermia, laser prostatectomy etc.)
3. Patients on corticosteroids
4. Concurrent treatment with immunosuppressive drugs (Imuran, cyclophosphamide etc.)
5. Uncontrolled infections (defined as viral, bacterial or fungal infections requiring specific therapy)
6. Human Immunodeficiency Virus (HIV) positive patients
7. Immunocompromised patients

Date of first enrolment

20/02/2001

Date of final enrolment

01/09/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre**Dept. Urology**

Rotterdam

Netherlands

3000 CA

Sponsor information**Organisation**

Erasmus Medical Centre (Netherlands)

Sponsor details

Dr Molewaterplein 40/50

Rotterdam

Netherlands

3000 CA

Sponsor type

University/education

Website

<http://www.erasmusmc.nl/>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands) - Revolving Fund

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	Results	01/07/2005		Yes	No