ISRCTN21565532 https://doi.org/10.1186/ISRCTN21565532

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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
17/10/2007

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
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.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
HSV-tk gene transduction, Ganciclovir

Primary outcome(s)
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 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.

Key secondary outcome(s))
To study and characterize the biological effects of and the immune response induced by adenovirus-mediated thymidine kinase gene therapy.

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 x 10^9/l, platelets = 100 x 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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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 immunosuppessive drugs (Imuran, cyclophosphamide etc.)
5. Uncontrolled infections (defined as viral, bacterial of 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)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands) - Revolving Fund

Results and Publications

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