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p53 immunotherapy in patients treated for metastasised colorectal cancer

Submission date	Recruitment status	[_] Prospectively registered
28/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/01/2021	Cancer	

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
P06.019, NL793, NTR806

Study information

Scientific Title
p53 immunotherapy in patients treated for metastasised colorectal cancer

Acronym
p53

Study objectives
p53 mutation in colorectal cancer provides an immunological window for immune therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Committee Medical Ethics, Leiden University Medical Center, on April 13 2006 (ref: P06.019).

Study design
Non-randomised clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tumour, Colorectal metastised cancer

Interventions
Patients will be vaccinated subcutaneously with a vaccine consisting of ten, overlapping long p53 peptides dissolved in the adjuvant Montanide ISA 51. Patients will be vaccinated two times with an interval of three weeks.

Intervention Type
Biological/Vaccine

Phase
Phase I/II

Primary outcome(s)
To define safety and immunogenicity of a p53 specific vaccine in combination with a defined adjuvant in patients treated for metastasised colorectal cancer.

Key secondary outcome(s))
To study the clinical response to vaccination.

Completion date
01/08/2008

Eligibility

Key inclusion criteria

1. Stage IV colorectal adenocarcinoma
2. At least three months after last treatment
3. Life expectance of more than six months
4. Patients must be 18 years of age or older
5. Female patients of childbearing potential must be neither pregnant nor breastfeeding and must have a negative serum pregnancy test within 14 days prior to entry. Female patients must agree to use effective contraception (birth control pills, condoms, approved implant, or Intra-Uterine Device [IUD]) during the course of this trial and for at least three months after the last injection
6. Patients must be ambulatory, with a World Health Organisation (WHO) performance status of one to two
7. Absence of any psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; conditions should be discussed with the patient before registration in the trial
8. Patient baseline laboratory values must be within the following ranges: Haemoglobin (Hb) more than 6 mmol/l; White Blood Cells (WBC) 3 x 10^9; serum creatinine less than 175 mmol/l
9. Before patient registration, written informed consent must be given to the patient, according to Dutch regulations
10. Patients must sign the written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Total final enrolment
10

Key exclusion criteria
1. History of autoimmune disease or systemic intercurrent disease which might affect immunocompetence
2. Other malignancies (previous or current), except adequately treated basal or squamous cell carcinoma of the skin
3.Significant co-morbid medical conditions that in the estimation of the investigator would preclude the patients safe participation in the study or may interfere with study objectives
4. Indication of active infectious disease, including Human Immunodeficiency Virus (HIV) and Hepatitis B infection
5. No radiotherapy, chemotherapy or other potentially immunosuppressive therapy administered within four weeks prior to vaccination
6. Receipt of another investigational product within the previous four weeks or at any time

during the study period
7. Receipt of prior p53 directed immunotherapy

Date of first enrolment
01/11/2006

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Center (LUMC) (The Netherlands)

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Center (LUMC) (The Netherlands)

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	01/02/2009	14/01/2021	Yes	No