

p53 immunotherapy in patients treated for metastasised colorectal cancer

Submission date 28/12/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/12/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/01/2021	Condition category Cancer	☐ 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
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).

Primary study design

Interventional

Study design

Non-randomised clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tumour, Colorectal metastasised 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 expectancy 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) 3×10^9 ; 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