TroVax® and cyclophosphamide treatment in colorectal cancer

Submission date	Recruitment status No longer recruiting	Prospectively registered		
10/12/2010		Protocol		
Registration date 05/04/2011	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
25/10/2022	Cancer			

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-vaccine-trovax-after-treatment-for-bowel-cancer-that-has-spread-tacticc

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

SPON868-10

Study information

Scientific Title

A pilot study to assess the effect of regulatory T cell depletion on 5T4-containing MVA (TROVAX®) vaccination in patients with INOPERABLE metastatic colorectal cancer

Acronym

TaCTiCC

Study objectives

This study will assess the efficacy of using either cyclophosphamide, or a pox virus based vaccine containing the tumour antigen 5T4 called TroVax® (Oxford BioMedica), or both, to deplete Tregs and enhance an immune response following completion of an initial 12 weeks of palliative chemotherapy. Patients who have inoperable metastatic disease will be recruited.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Interventional multicentre randomised 2 x 2 factorial design pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

- 1. Group 1: Control. No additional treatment unless clinically indicated.
- 2. Group 2: Metronomic cyclophosphamide 50mg bd (oral) as single agent on weeks 1 (14 doses) and on week 3 (12 doses)
- 3. Group 3: Vaccination (i.m.) TroVax® (1 x 109 TCID50/mL) at week 1, 3, 5, 7, 9 and 13
- 4. Group 4: Metronomic cyclophosphamide 50 mg bd (oral) on weeks 1 (14 doses) and week 3 (12 doses), followed by i.m. TroVax® (1 x 109 TCID50/mL) on weeks 4, 6, 8, 10, 12 and 16

Intervention Type

Drug

Phase

Phase I/II

Drug/device/biological/vaccine name(s)

TroVax®

Primary outcome(s)

- 1. Reduction in the frequency and/or function of Tregs measured in blood samples in patients treated with metronomic cyclophosphamide and/or TroVax® compared to patients not receiving cyclophosphamide
- 2. Development or increase in T cell responses in patients treated with cyclophosphamide and /or TroVax® versus untreated patients

3. Increase in anti-tumour immune responses measured in blood samples in patients treated with the vaccine TroVax® plus metronomic cyclophosphamide compared to TroVax® alone or no TroVax® group

Key secondary outcome(s))

- 1. Overall Survival as the time in days from randomisation until death of any cause censoring at date of last follow up
- 2. Time To Progression with death as a competing risk will be measured as the time in days from randomisation until disease progression as determined by RECIST criteria for radiological imaging and clinical assessment
- 3. Progression Free Survival will be measured as the time in days from randomisation until progression or death of any cause censoring at date of last follow up

Completion date

23/06/2016

Eligibility

Key inclusion criteria

- 1. Patient able to give informed consent personally or through a legal representative
- 2. Signed and dated written informed consent
- 3. Aged greater than or equal to 18 years, either sex
- 4. Clinical diagnosis of inoperable colorectal cancer
- 5. World Health Organization (WHO) performance status 0 2
- 6. Responding or stable disease as defined by oncologist following 12 weeks of chemotherapy as demonstrated on computed tomography (CT) scan in comparison with pre-treatment CT scan (Response Evaluation Criteria in Solid Tumours [RECIST])
- 7. Subject is clinically immunocompetent
- 8. Any cancer related symptoms are under control with standard non-chemotherapy medications
- 9. Subject has adequate bone marrow function as defined by an absolute lymphocyte count greater than or equal to $500/\mu L$, absolute neutrophil count greater than $1200/\mu L$ and platelet count greater than $100,000/\mu L$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

52

Key exclusion criteria

- 1. Patient unable to give informed consent personally or through a legal representative
- 2. Creatinine level greater than 1.5 x upper limit of normal (ULN)
- 3. Bilirubin level greater than 50 µmol/l
- 4. Alkaline phosphatase greater than 3 x ULN
- 5. Aspartate aminotransferase (AST) and alanine aminotransferase ALT) greater than 2 x ULN
- 6. Prothrombin time greater than 18 seconds
- 7. Prior exposure to TroVax®
- 8. Life expectancy of less than 3 months
- 9. Diagnosed as being immunosupressed, receiving oral steroids (nasal sprays and inhalers are permitted) or receiving immunosuppressive therapy for oncology disorders, or following transplant
- 10. Patient has completed chemotherapy more than 2 weeks from the start of the treatment
- 11. Subject has clinically apparent/active autoimmune disease (prior confirmed diagnosis or treatment for autoimmune disease including Systemic Lupus Erythematosis, Grave's disease, Hashimoto's thyroiditis, multiple sclerosis, insulin dependent diabetes mellitus and rheumatoid arthritis). Note: subjects with non-insulin dependent diabetes mellitus can be included, as can subjects with controlled and rarely flaring rheumatoid disease.
- 12. Subject has a platelet count prior to start of chemotherapy greater than 400,000/ μ L; monocytes greater than 80,000/ μ L; haemoglobin less than 9 g/dL
- 13. Significant cancer related symptoms requiring immediate treatment with chemotherapy
- 14. "Currently active" second malignancy, other than non-melanoma skin cancer. Subjects are not considered to have a "currently active" malignancy if they have completed therapy more than 5 years previously and have no known evidence of residual or recurrent disease.
- 15. Evidence of significant clinical disorder or laboratory finding which in the opinion of the investigating physician makes it undesirable for the patient to participate in the trial. No participant should have a serious or uncontrolled intercurrent infection (including those positive for HIV).
- 16. Psychiatric illnesses/social situations that limit compliance with protocol requirements
- 17. Allergy to egg proteins, cyclophosphamide, neomycin or allergic response to vaccinia vaccines
- 18. Known cerebral metastases (known from previous investigations or clinically detectable)
- 19. Haemorrhagic cystitis
- 20. Severe infection

Date of first enrolment 01/04/2011

Date of final enrolment 31/03/2014

Locations

Countries of recruitment

United Kingdom

Wales

Henry Wellcome Building

Cardiff United Kingdom CF14 4XN

Sponsor information

Organisation

Cardiff University (UK)

ROR

https://ror.org/03kk7td41

Funder(s)

Funder type

Charity

Funder Name

Cancer Research Wales

Alternative Name(s)

Ymchwil Canser Cymru, CRW

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	12/10/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			25/10/2022	No	Yes