# TroVax® and cyclophosphamide treatment in colorectal cancer

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
10/12/2010		☐ Protocol		
<b>Registration date</b> 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

Dr Andrew Godkin

#### Contact details

Henry Wellcome Building School of Medicine Heath Park Cardiff United Kingdom CF14 4XN

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

# 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 measure

- 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

#### Secondary outcome measures

- 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

## Overall study start date

01/04/2011

#### 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

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

54

#### 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/ $\mu$ L; monocytes greater than 80,000/ $\mu$ 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

Study participating centre Henry Wellcome Building

Cardiff United Kingdom CF14 4XN

# **Sponsor information**

## Organisation

Cardiff University (UK)

#### Sponsor details

Research and Commercial Division 7th floor 30-36 Newport Road Cardiff Wales United Kingdom CF24 0DE

#### Sponsor type

University/education

#### Website

http://www.cardiff.ac.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**

# Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

# 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	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/10/2017		Yes	No
Plain English results			25/10/2022	No	Yes