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A Cancer Research UK phase I trial of adoptive transfer of autologous tumour antigen specific T-cells with pre-conditioning chemotherapy and intravenous interleukin-2 (IL2) in patients with advanced carcinoembryonic antigen (CEA) positive tumours

Submission date 30/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/06/2010	**Overall study status** Completed	
Last Edited 06/03/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-mfez-t-cells-chemotherapy-and-il2-for-cancers-that-test-positive-for-carcinoembryonic-antigen

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

2005-004085-16

IRAS number

ClinicalTrials.gov number
NCT01212887

Secondary identifying numbers
6499

Study information

Scientific Title
A Cancer Research UK phase I trial of adoptive transfer of autologous tumour antigen specific T-cells with pre-conditioning chemotherapy and intravenous interleukin-2 (IL2) in patients with advanced carcinoembryonic antigen (CEA) positive tumours

Acronym
MFEz Study

Study objectives
This trial proposes to use engineered T cells (MFEz T cells) comprising polyclonal CD4 and CD8 populations in place of the selected, specific TILs and combines these with 'supportive therapies' of pre-conditioning chemotherapy and high dose intravenous IL2.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: GTAC096)

Study design
Single centre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: All Cancers/Misc Sites; Disease: All

Interventions
Patients will receive pre-conditioning chemotherapy followed by MFEz T cells and then intravenous IL2. The pre-conditioning chemotherapy regime and the dose of MFEz T cells will be determined by the dose escalation scheme. Chemotherapy will only be commenced if adequate transduction and expansion of MFEz T cells has occurred. One cycle only of chemotherapy and MFEz T cells will be given. Further cycles of IL2 may be considered if specified criteria are met.

Study entry: registration only

Intervention Type
Other

Phase
Phase I

Primary outcome measure
To evaluate the feasibility of using MFEz T cells

Secondary outcome measures
1. To determine dose of MFEz T cells that gives the highest frequency in the circulation as measured
2. Adverse event assessment for as long as the patient is able to attend clinic according to CTCAE

Overall study start date
29/11/2007

Completion date
17/05/2010

Eligibility

Key inclusion criteria
1. Have histologically confirmed malignancy that is CEA positive that is metastatic or unresectable and for which standard curative or palliative measures:
1.1. Do not exist
1.2. Are no longer effective
1.3. Have been completed
1.4. Have been refused
2. Provide written (signed and dated) informed consent and be capable of co-operating with treatment and follow-up
3. Be 18 years or over, either sex
4. Have a life expectancy of at least 3 months
5. Have a World Health Organization (WHO) performance status of 0 or 1
6. Female patients of child-bearing potential are eligible, provided they have a negative serum or urine pregnancy test prior to enrolment and agree to use appropriate medically approved contraceptive precautions for four weeks prior to leukapheresis, during the trial, and for six months afterwards
7. Male patients must agree to use barrier method contraception during the trial and for six months afterwards

8. Patients receiving cyclophosphamide must have a left ventricular ejection fraction (LVEF) of greater than or equal to 50% on multiple gated acquisition (MUGA) scan (within 4 weeks prior to leukapheresis)
9. Patients must have haematological and biochemical indices within the following ranges at screening. These measurements must be repeated to confirm eligibility between leukapheresis and commencing chemotherapy.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 22; UK sample size: 22

Key exclusion criteria
1. Radiotherapy (except for palliative reasons), endocrine therapy, immunotherapy or chemotherapy during the previous four weeks (six weeks for nitrosureas and Mitomycin-C) prior to treatment with chemotherapy in the trial or during the course of the trial.
2. Toxic manifestations of previous treatments. Exceptions to this are alopecia or certain grade 1 toxicities which in the opinion of the Investigator and CRUK should not exclude the patient (grade 1 neuropathy or grade 1 fatigue).
3. Primary brain tumours or brain metastases
4. Major thoracic and/or abdominal surgery from which the patient has not yet recovered
5. At high medical risk because of non-malignant systemic disease including active uncontrolled infection
6. Known to be serologically positive for hepatitis B, hepatitis C, human immunodeficiency virus (HIV) or human T cell lymphotropic virus (HTLV)
7. History of autoimmune disease
8. Inflammatory bowel disease
9. Concurrent congestive heart failure or prior history of class III - IV cardiac disease (New York Heart Association [NYHA])
10. Prior bone marrow transplant or have had extensive radiotherapy to greater than 25% of bone marrow
11. Patients who are taking, or likely to require systemic steroids or other immunosuppressive therapy
12. Current malignancies originating from other primary sites, with the exception of adequately treated cone-biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin
13. Participation in any other clinical trial within the previous 30 days prior to leukapheresis or during the course of this trial
14. Concurrent serious infections within the 28 days prior to leukapheresis
15. Any other condition which in the Investigator's opinion would not make the patient a suitable candidate for the clinical trial

Date of first enrolment
29/11/2007

Date of final enrolment
17/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Medical Oncology
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Christie Hospital NHS Foundation Trust (UK)

Sponsor details
Wilmslow Road
Manchester
England
United Kingdom
M20 4BX

Sponsor type
Hospital/treatment centre

Website
http://www.christie.nhs.uk/

ROR
https://ror.org/03v9efr22

Funder(s)

Funder type

Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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

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	01/11/2017		Yes	No