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T4 immunotherapy of head and neck cancer

Submission date 15/07/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 15/07/2015	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 02/12/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-t4-immunotherapy-for-people-with-head-and-neck-cancer

Contact information

Type(s)
Public

Contact name
Dr John Maher

Contact details
Department of Research Oncology
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Additional identifiers

Clinical Trials Information System (CTIS)
2012-001654-25

ClinicalTrials.gov (NCT)
NCT01818323

Protocol serial number
19183

Study information

Scientific Title
Phase 1 trial: T4 immunotherapy of head and neck cancer

Study objectives
Intra-tumoural delivery of T4 immunotherapy will provide a safe and efficacious immunotherapy for locally advanced / recurrent squamous cell carcinoma of head and neck.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee west London, 20/11/2012, ref: 12/LO/1834

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Head and Neck Cancer; Disease: Head and Neck

Interventions
Intratumoural T4 immunotherapy, delivered at a single setting to multiple points in a locally advanced or recurrent tumour.
Study Entry : Registration only

Intervention Type
Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
T4

Primary outcome(s)
To define dose limiting toxicities for T4 immunotherapy in SCCHN.

Key secondary outcome(s))
1. To determine a safe and feasible recommended dose for phase II testing of intra-tumoural T4 Immunotherapy
2. To investigate serum cytokine levels after administration of T4 immunotherapy
3. To investigate persistence of T4+ T-cells at the site of administration and in the peripheral circulation
4. To achieve preliminary assessment of anti-tumour activity, using cross-sectional imaging to quantify objective responses

5. To investigate tumour ErbB receptor phenotype, before and after administration of T4 immunotherapy
6. To investigate immunomodulatory effects of low dose cyclophosphamide on T4 immunotherapy.
7. To investigate effect of T4 immunotherapy upon immune reactivity against endogenous tumour antigens

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Histologically and/ or cytologically confirmed SCCHN
2. 18 years or older
3. Locally advanced and/ or recurrent head and neck cancer with or without metastatic disease (excluding brain metastases) for whom no standard therapy remains or is suitable
4. Regarding previous treatment, patients may have received prior systemic therapy, including platinum chemotherapy, at least one month earlier. In the presence of metastatic disease, recent short-course palliative radiotherapy to non-target site(s) is allowed
5. Those who refuse palliative treatment may be eligible for participation. However, their reasons for not opting for palliative treatment must be explored thoroughly
6. At least one loco-regional target lesion measurable by RECIST v1.1 criteria on CT or MRI scanning within four weeks of enrolment, and amenable to intra-tumoral injection
7. Eastern Co-operative Oncology Performance Status of 0-2
8. Normal cardiac function as assessed by electrocardiography and either echocardiography (ECHO), or multi-gated aquisition (MUGA) scanning. Left ventricular ejection fraction must be >50%. Assessment must take place within four weeks of enrolment
9. Haematology results within seven days of enrolment: neutrophilis >1.5 x 109/L, platelets >100 x 109/L, haemoglobin >9g/dl, INR <1.5
10. Biochemistry results within seven days of enrolment:
10.1. Serum creatinine <1.5 upper limit of normal
10.2. Bilirubin <1.25 times normal
10.3. ALT/ AST <2.5 times upper limit of normal (<5 times upper limit of normal if liver metastases present)
11. Female patients must be postmenopausal (12 months of amenorrhea), surgically sterile or they must agree to use a physical method of contraception. Oral or injectable contraceptive agents cannot be the sole method of contraception. Women of childbearing potential (WOCB) who receive cyclophosphamide must adhere to these contraceptive requirements during the trial and until 3 months after the last dose of cyclophosphamide. Male patients, even if sterlized, must agree to use a barrier method of contraception. Male subjects must also commit to use a barrier method of contraception until at least 3 months after the end of study treatment
12. Written informed consent prior to registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. The presence of or imminent occurrence of airway obstruction, unless tracheostomy in place
2. The presence of or imminent occurrence of tumour-mediated infiltration of major blood vessels
3. Positive history of HIV-1, HIV-2, HTLV-1, HTLV-2, Hepatitis B, Hepatitis C or syphilis infection.
4. Prior splenectomy
5. Clinically active autoimmune disease. Sub-clinical or quiescent autoimmune disease does not exclude from participation
6. Treatment in the preceding week with systemic corticosteroids (> 20mg prednisolone/ day), any systemic immunomodulatory agent, radiotherapy, chemotherapy or investigational medicinal product
7. Concurrent use of anticoagulant therapy is not permissible
8. The presence of major co-morbidity likely to impair ability to undergo trial therapy, such as recent myocardial infraction, congestive cardiac failure or uncontrolled hypertension
9. The presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
10. Cyclophosphamide allergy - Final (sixth) cohort only
11. Pregnancy
12. Prior T4 immunotherapy

Date of first enrolment
05/06/2015

Date of final enrolment
15/10/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Department of Research Oncology, Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Jon Moulton Charitable Foundation

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		15/06/2023	12/12/2023	Yes	No
Other files			02/12/2025	No	No
Protocol file	version 2.5	31/05/2015	12/12/2023	No	No
Protocol file	version 10	29/01/2024	24/11/2025	No	No
Statistical Analysis Plan			02/12/2025	No	No