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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	[_] Statistical analysis plan [_] Results
Last Edited 04/12/2024	**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

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Additional identifiers

EudraCT/CTIS number
2012-001654-25

IRAS number

ClinicalTrials.gov number
NCT01818323

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
To define dose limiting toxicities for T4 immunotherapy in SCCHN.

Secondary outcome measures
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

Overall study start date
05/06/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 21; UK Sample Size: 21; Description: Six cohorts of 3 patients each plus one expansion cohort of 3 patients

Total final enrolment
25

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
England

United Kingdom

Study participating centre
Department of Research Oncology, Guy's Hospital
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Sponsor information

Organisation
King's College London

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Strand
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Sponsor type
University/education

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

Publication and dissemination plan
The analysed results of the completed phase 1 trial will be published in a peer-reviewed journal

Intention to publish date
31/12/2025

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
Protocol file	version 2.5	31/05/2015	12/12/2023	No	No