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[18F]-tetrafluoroborate in patients with primary thyroid cancer or salivary cancer

Submission date	Recruitment status	[_] Prospectively registered
19/11/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-pet-ct-scans-to-detect-thyroid-cancer-and-salivary-gland-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2014-001925-33

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19094

Study information

Scientific Title
A phase I trial of [18F]-tetrafluoroborate in patients with primary thyroid cancer or salivary cancer to study biodistribution and uptake in tumours and normal NIS expressing tissue

Acronym
BF4

Study objectives
The aim of this study is to investigate whether tetrafluoroborate has any side effects and if it specifically targets cancers that express the hNIS transporter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Borders Research Ethics Committee, 29/12/2014, ref: 14/LO/1247

Study design
Non-randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Cannula inserted into each arm for the administration of the radioactive material and the taking of blood samples.

Intervention Type
Drug

Phase

Phase I

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

Primary outcome measure
To assess the biodistribution of [18F]tetrafluoroborate in vivo

Secondary outcome measures
Not provided at time of registration

Overall study start date
14/09/2015

Completion date
02/08/2017

Eligibility

Key inclusion criteria
1. Aged 18-80 years
2. Women of childbearing potential must have documented negative pregnancy test on day 1, prior to (18F)BF4-administration
3. Diagnosis of a malignancy of the thyroid or a malignancy of a salivary gland
4. All patients have to be suitable for surgical treatment as part of their normal management
5. Able to comply with treatment plans, scheduled visits, all study PET imaging and follow-up
6. Willing to give informed consent
7. Not be taking thyroid mediciation or iodine containing medication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Total final enrolment
5

Key exclusion criteria
1. Previous ionising radiation exposure for research purposes or exposure to any previous experimental medicine that might affect the uptake of BF4 would exclude the patient from this ionising radiation study
2. Patients without adequate understanding of written or spoken English would not be able to participate in this study as translation of the patient information sheet will not be possible
3. Any prior treatment for the thyroid or salivary gland tumours
4. Pregnancy or lactation
5. Any other problems that may make the patient unable to tolerate the PET scans or translational biopsies
6. Ingestion of iodine containing medication (eg amiodarone) within preceding 12 months, administration of iv contrast media within 6 months or thyroid hormones within 2 months

Date of first enrolment
14/09/2015

Date of final enrolment
02/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
The Rayne Institute
4th Floor Lambeth Wing
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London

Sponsor details
Strand
London

England
United Kingdom
WC2R 2LS

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King's Health Partners

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/04/2017	07/08/2020	Yes	No
Plain English results		26/07/2021	29/07/2021	No	Yes
HRA research summary			28/06/2023	No	No