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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

**Contact name**
Dr Maite Jauregui-Osoro

**Contact details**
King's College London
The Rayne Institute
4th Floor Lambeth Wing
Westminster Bridge Road
London
United Kingdom
SE1 7EH

## Additional identifiers

**Clinical Trials Information System (CTIS)**
2014-001925-33

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
To assess the biodistribution of [18F]tetrafluoroborate in vivo

## Key secondary outcome(s))
Not provided at time of registration

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
80 years

### Sex
All

### 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**
United Kingdom

England

**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

**ROR**
https://ror.org/0220mzb33

# Funder(s)

**Funder type**
University/education

**Funder Name**
King's Health Partners

# Results and Publications

**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 |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Plain English results | | 26/07/2021 | 29/07/2021 | No | Yes |