# Clinical trial results:
# A Phase II, single-centre exploratory study to assess the value of hypoxia imaging with [18F]HX4 PET/CT in predicting outcome for patients with squamous cell carcinoma of head and neck and non-small cell lung cancer undergoing radical radiotherapy with curative intent (OXYPET Study)

## Summary

| | |
|---|---|
| EudraCT number | 2013-003563-58 |
| Trial protocol | GB |
| Global end of trial date | 25 July 2017 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 08 August 2018 |
| First version publication date | 08 August 2018 |
| Summary attachment (see zip file) | Summary of Results (OXYPET_ResultsSummary_16Jul18.pdf) |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | PET_HX4_01 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Nottingham University Hospitals NHS Trust |
| Sponsor organisation address | Queen's Medical Centre, Derby Road, Nottingham, United Kingdom, NG7 2UH |
| Public contact | Helen Betts, Nottingham University Hospitals NHS Trust, 0044 01159709172, helen.betts2@nuh.nhs.uk |
| Scientific contact | Helen Betts, Nottingham University Hospitals NHS Trust, 0044 01159709172, helen.betts2@nuh.nhs.uk |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 25 July 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 25 July 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 July 2017 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

Do the scan results from the hypoxia imaging (HX4 PET/CT) predict patient outcome two years after treatment?

Protection of trial subjects:

Adverse events were monitored up to 72 hours post HX4 administration. No special measures required.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 31 March 2015 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | United Kingdom: 3 |
| Worldwide total number of subjects | 3 |
| EEA total number of subjects | 3 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 2 |
| From 65 to 84 years | 1 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Eight eligible patients consented to take part. Only three out of eight participants had the HX4 PET/CT scan due to scheduling difficulties.

### Pre-assignment

Screening details:

Patients were screened for eligibility by consultant oncologists at clinic appointments. Interested patients were given the trial information sheet. Consent was signed at the next appointment.
In addition to the eight consented patients, two further patients were interested but exclusion criteria applied (low kidney function and too unwell).

### Period 1

| | |
|---|---|
| Period 1 title | Overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

### Arms

| | |
|---|---|
| **Arm title** | [18F]HX4 PET/CT scan |

Arm description:

Each participant had a single pre-treatment [18F]HX4 PET/CT scan.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | [18F]HX4 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

370 MBq intravenous injection

| **Number of subjects in period 1** | [18F]HX4 PET/CT scan |
|---|---|
| Started | 3 |
| Completed | 3 |

## Baseline characteristics

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | [18F]HX4 PET/CT scan |
| Reporting group description: | |
| Each participant had a single pre-treatment [18F]HX4 PET/CT scan. | |

### Primary: Two year patient outcome

| | |
|---|---|
| End point title | Two year patient outcome[1] |
| End point description: | |
| Patients to be grouped and analysed with reference to hypoxia status from the HX4 PET/CT scan results. | |
| End point type | Primary |
| End point timeframe: | |
| Two years post radiotherapy treatment. | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Recruitment was closed after only three participants had undergone the [18F]HX4 PET/CT scan, because [18F]HX4 was no longer available to the investigators. Two year follow up was not collected for the three participants. Statistical analysis was not warranted.

| End point values | [18F]HX4 PET/CT scan | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0[2] | | | |
| Units: number of patients | | | | |
| primary treatment failure<br>disease free survival<br>tumour recurrence | | | | |

Notes:

[2] - Two year follow up data not collected due to insufficient recruitment.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Five year outcome

| | |
|---|---|
| End point title | Five year outcome |
| End point description: | |
| Assessment of predictive value of the HX4 PET/CT scan on treatment outcome 5 years after radiotherapy treatment. | |
| End point type | Secondary |
| End point timeframe: | |
| Five years post radiotherapy treatment | |

| End point values | [18F]HX4 PET/CT scan | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0[3] | | | |
| Units: Patient number | | | | |
| disease free survival<br>tumour recurrence | | | | |

Notes:

[3] - Two and five year follow up data not collected due to insufficient recruitment.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Comparison of [18F]HX4 with [18F]FDG PET/CT for prognostic value

| End point title | Comparison of [18F]HX4 with [18F]FDG PET/CT for prognostic value |
|---|---|

End point description:

Comparison of pre-treatment [18F]HX4 PET/CT scans with [18F]FDG PET/CT scans in relation to treatment outcome data, to determine if [18F]HX4 PET/CT adds value to [18F]FDG PET/CT imaging for predicting patient outcome.

| End point type | Secondary |
|---|---|

End point timeframe:

Two years and five years post-radiotherapy treatment.

| End point values | [18F]HX4 PET/CT scan | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0[4] | | | |
| Units: number of patients | | | | |

Notes:

[4] - Two and five year follow up data not collected due to insufficient recruitment.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Comparison of lesion size with intensity of HX4 uptake

| End point title | Comparison of lesion size with intensity of HX4 uptake |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

No time frame defined.

| End point values | [18F]HX4 PET/CT scan | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0[5] | | | |
| Units: cm3 and standardised uptake value | | | | |
| number (not applicable) | | | | |

Notes:

[5] - Insufficient recruitment to provide conclusions.

## Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information[1] | |
|---|---|
| Timeframe for reporting adverse events:<br>72 hours post injection of [18F]HX4 | |
| Assessment type | Non-systematic |

| Dictionary used | |
|---|---|
| Dictionary name | Not required |
| Dictionary version | 0 |

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Three participants underwent the [18F]HX4 scan, and no adverse events were encountered. This was in line with expectations from the reference safety information.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 12 December 2013 | Addition of urine pregnancy test for female participants of reproductive capacity, prior to [18F]HX4 PET/CT scan. |
| 19 December 2013 | Submission of updated Investigator Brochure. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported