



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				
disease free survival				
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				
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:

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