



Clinical trial results:

Non invasive imaging of [18F]HX4 with Positron-Emission-Tomography (PET) in Head and Neck Cancer.

Summary

EudraCT number	2011-001812-80
Trial protocol	NL
Global end of trial date	25 August 2015

Results information

Result version number	v1 (current)
This version publication date	16 February 2024
First version publication date	16 February 2024
Summary attachment (see zip file)	Article 2015 (2015 Zegers ActaOncol Imaging of tumour hypoxia and metabolism HNSCC.pdf)

Trial information

Trial identification

Sponsor protocol code	11-12-23/03-intern-6470
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01347281
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Maastr
Sponsor organisation address	Dr. Tanslaan 12, Maastricht, Netherlands,
Public contact	Maastr Clinic, Maastr Clinic, 0031 0884455600, philippe.lambin@maastro.nl
Scientific contact	Maastr Clinic, Maastr Clinic, 0031 0884455600, philippe.lambin@maastro.nl

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	18 March 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 August 2015
Global end of trial reached?	Yes
Global end of trial date	25 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determine if tumor hypoxia can be accurately visualised with [18F]HX4 PET imaging in head and neck cancer tumors

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2011
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	Netherlands: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	16
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Eligible patients with head and neck squamous cell carcinoma (HNSCC) of the oral cavity, oropharynx, hypopharynx, larynx (T2, T3, T4, any N, M0), tumor diameter $\geq 2,5$ cm, planned to be treated with curative primary radiation treatment (+/- concurrent chemotherapy) are included.

Pre-assignment

Screening details:

HNSCC

Period 1

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

Blinding implementation details:

Not blinded

Arms

Arm title	HX4 injection
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Arm description:

HX4

Arm type	Experimental
Investigational medicinal product name	HX4
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

444 MBq (12 mCi) [^{18}F]HX4

Number of subjects in period 1	HX4 injection
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	Baseline
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Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	20	20	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
median	60		
standard deviation	± 1	-	
Gender categorical			
Units: Subjects			
Female	3	3	
Male	17	17	

End points

End points reporting groups

Reporting group title	HX4 injection
Reporting group description: HX4	
Subject analysis set title	Per protocol
Subject analysis set type	Per protocol
Subject analysis set description: Per protocol	

Primary: Visualisation of tumor hypoxia with [18F] HX4 PET imaging

End point title	Visualisation of tumor hypoxia with [18F] HX4 PET imaging ^[1]
End point description:	

End point type	Primary
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End point timeframe:

After scan

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: An article was included.

End point values	HX4 injection			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: 20				
number (not applicable)	20			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From inclusion until after scanning period

Assessment type	Non-systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	3.0
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Frequency threshold for reporting non-serious adverse events: 1 %

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: An article is included.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 August 2013	Less scans and additional analysis
29 November 2013	New supplier of HX4

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

NA

Notes: