Clinical trial results:
Prospektive Evaluation von Multimodality Imaging Verfahren (PET - CT - MRT - US - Bildfusion) bei malignen Tumoren der Kopf-Hals-Region

Summary

EudraCT number	2007-004393-81
Trial protocol	AT
Global end of trial date	28 April 2009

Results information

Result version number	v1 (current)
This version publication date	11 August 2022
First version publication date	11 August 2022

Trial information

Trial identification

Sponsor protocol code	unknown

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020
Public contact	OA Dr. Gerlig Widmann, University Hospital for Radiology, Anichstrasse 35, 6020 Innsbruck, +43 (0)512 504 80927, gerlig.widmann@tirol-kliniken.at
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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	28 April 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 April 2009
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Primumdiagnostik, CUP-Syndrom, Rezidivdiagnostik, Fernmetastastasen- und Zweittumordiagnostik: Bei angenommener Sensitivität von 80 % mit einem 95 %-Konfidenzintervall von [70 %, 90 %] (also zweiseitig) ergibt sich eine Mindestfallzahl von jeweils 62. Bei angenommener Sensitivität von 90 % sinkt die Mindestfallzahl für das 95%-Konfidenzintervall [80%, 100%] auf 35.

LK-Staging: Bei angenommener Sensitivität von 80 % mit einem 95 %-Konfidenzintervall von [70 %, 90 %] (also zweiseitig) ergibt sich eine Mindestfallzahl von 62 Patienten je LK-Level.

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	29 April 2008
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	Austria: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Treatment
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Visipaque 320 mg K/ml
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Investigational medicinal product name	Efdege
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Investigational medicinal product name	Multihance
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Number of subjects in period 1	Treatment
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Treatment
Reporting group description:	
No patients were enrolled in this trial. "99999" is a value for 0 participants.	

Reporting group values	Treatment	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description: -

Primary: Evaluation of Multimodality Imaging

End point title	Evaluation of Multimodality Imaging[1]

End point description:

End point type	Primary

End point timeframe:

N/A

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: No patients were enrolled in this trial, therefore no statistical analysis was performed.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: N/A				
number (not applicable)	1			

Notes:

[2] - "99999" is a value for 0 participants

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 29.04.2008-28.04.2009	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	3.0

Frequency threshold for reporting non-serious adverse events: 5 %

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: No patients were enrolled in this trial, therefore no AEs or SAEs were observed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

No patients were enrolled in this trial. "99999" is a value for 0 participants.

Notes: