



Clinical trial results:

PROSPECTIVE STUDY OF [68GA]NODAGA-RGD-PET FOR THE DIAGNOSIS OF HEPATOCELLULAR CARCINOMA AND THE ASSESSMENT OF TREATMENT RESPONSE

Summary

EudraCT number	2013-003741-42
Trial protocol	AT
Global end of trial date	01 July 2015

Results information

Result version number	v1 (current)
This version publication date	21 October 2020
First version publication date	21 October 2020

Trial information

Trial identification

Sponsor protocol code	31031981
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Innsbruck
Sponsor organisation address	Anichstrasse 35, Innsbruck, Austria,
Public contact	Armin Finkenstedt, Medizinische Universität Innsbruck, Abteilung für Gastroenterologie und Hepatologie, 0043 512504, armin.finkenstedt@tirol-kliniken.at
Scientific contact	Armin Finkenstedt, Medizinische Universität Innsbruck, Abteilung für Gastroenterologie und Hepatologie, 0043 512504, armin.finkenstedt@tirol-kliniken.at

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	04 January 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 July 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate accumulation of [68Ga]NODAGA-RGD tracer in HCC compared to the surrounding liver parenchyma and to correlate the tumor volume measured by [68Ga]NODAGA-RGD-PET to the tumor volume measured by CT/MRI.

Protection of trial subjects:

Data are published in anonymized form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2014
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: 9
Worldwide total number of subjects	9
EEA total number of subjects	9

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)	7
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

- Yet untreated HCC due to liver cirrhosis Child Pugh class A or class B. The diagnosis of HCC has to be confirmed by multiphasic CT or MRI according to EASL/EORTC guidelines.
- Written informed consent
- Age 18 or above
- In women, pregnancy must be excluded and contraception must be performed

Pre-assignment

Screening details:

- Yet untreated HCC due to liver cirrhosis Child Pugh class A or class B. The diagnosis of HCC has to be confirmed by multiphasic CT or MRI according to EASL/EORTC guidelines.
- Written informed consent
- Age 18 or above
- In women, pregnancy must be excluded and contraception must be performed

Pre-assignment period milestones

Number of subjects started	9
Number of subjects completed	9

Period 1

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

Arms

Arm title	only one arm
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Arm description:

study arm

Arm type	Experimental
Investigational medicinal product name	[68Ga]NODAGA
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:

1. Peptide (diagnostic) doses: 20 µg NODAGA-RGD
 2. Radiation (imaging) dose: 68Ga @ 150 MBq (±25%)
- All doses are presented as isotonic sodium chloride solution for intravenous injection.

Number of subjects in period 1	only one arm
Started	9
Completed	9

Baseline characteristics

End points

End points reporting groups

Reporting group title	only one arm
Reporting group description: study arm	

Primary: To determine the diagnostic accuracy of [68Ga]NODAGA-RGD-PET in patients with HCC in comparison to contrast enhanced CT or MRI

End point title	To determine the diagnostic accuracy of [68Ga]NODAGA-RGD-PET in patients with HCC in comparison to contrast enhanced CT or MRI ^[1]
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End point description:

- Whole body 3D PET/CT images will be acquired at 0-1 h (dynamic) followed by a static scan (6 patients), or 5, 20, 45 and 90 min (static) post-injection (10 patients) with low-dose CT for attenuation and scatter correction (AC, SC).
- PET/CT images will be analysed for organ pharmacokinetics, tumour targeting (visual and semi-quantitatively), and internal dosimetry (MIRD).
- Serial blood sampling and urine collection to determine tracer stability is carried over 60 min p.i.

End point type	Primary
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End point timeframe:

During study

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: due to study nature no statistical analysis

End point values	only one arm			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: radiation				
arithmetic mean (standard deviation)	1 ($\pm$ 1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

During study participation. No adverse Events have been observed.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1.0
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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: No adverse Events have been observed during the study

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

None reported