

**Clinical trial results:****Diagnostic and clinical value of fused $^{64}\text{CuCl}_2$ -PET/MRI in prostate cancer relapse. Comparison with multiparametric MRI (mpMRI) and ^{18}F -Choline-PET/MRI****Summary**

EudraCT number	2014-005140-18
Trial protocol	IT
Global end of trial date	31 October 2016

Results information

Result version number	v1 (current)
This version publication date	28 July 2021
First version publication date	28 July 2021
Summary attachment (see zip file)	Diagnostic value of retrospectively fused $^{64}\text{CuCl}_2$ PET/MRI in biochemical relapse of prostate cancer: comparison with fused ^{18}F Choline PET/MRI, $^{64}\text{CuCl}_2$ PET/CT, ^{18}F Choline PET/CT, and mpMRI (Abdominal Radiology May 2020.pdf) $^{64}\text{CuCl}_2$ PET/CT in Prostate Cancer Relapse (J Nucl Med 2018 59444-451.pdf) Biokinetic and dosimetric aspects of $^{64}\text{CuCl}_2$ in human prostate cancer: possible theranostic implications (Righi et al. EJNMMI Research (2018) 818.pdf)

Trial information**Trial identification**

Sponsor protocol code	RAME-01
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Rame01: 30UCS2014

Notes:

Sponsors

Sponsor organisation name	E.O. Ospedali Galliera
Sponsor organisation address	Mura delle Cappuccine 14, Genoa, Italy, 16128
Public contact	Ufficio del Coordinatore Scientifico, E.O.Ospedali Galliera - Genova, 0039 0105634235, ucs@galliera.it
Scientific contact	Ufficio del Coordinatore Scientifico, E.O.Ospedali Galliera - Genova, 0039 0105634235, ucs@galliera.it

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
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Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2016
Global end of trial reached?	Yes
Global end of trial date	31 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study was firstly to assess the diagnostic performance of fused $^{64}\text{CuCl}_2$ -PET/MRI in patients with suspected relapse of prostate cancer after surgery or EBRT. In addition we want to compare the accuracy of fused $^{64}\text{CuCl}_2$ -PET/MRI with that of mMRI, ^{18}F -Choline-PET/MRI, ^{18}F -Choline-PET/CT, and contrast enhanced CT in detecting local recurrence, lymph node, and bone metastases

Protection of trial subjects:

To evaluate the potential hepatic radiotoxicity of $^{64}\text{CuCl}_2$ administration, according to Agenzia Italiana del Farmaco suggestions, bloodtests were performed on all patients and used to determine the following parameters: hematocrit, hemoglobin, C-reactive protein, aspartate transaminase, alanine transaminase, alkaline phosphatase, albumin, total bilirubin, γ -glutamyl transferase, lactate dehydrogenase, total proteins, serum creatinine, and azotemia. The tests were performed immediately before radiopharmaceutical administration and 10 d after the first $^{64}\text{CuCl}_2$ whole-body scan.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 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	Italy: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	15
From 65 to 84 years	31
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

Prostate Cancer patients presenting biochemical relapse after first-line surgery or EBRT

Pre-assignment

Screening details:

Principal inclusion criteria (up to 4000 characters)(Criteri di inclusione principali, in inglese):

-years > 18

-all histologically proven prostate cancer patients who showed biochemical relapse after surgery or first-line treatment with radiotherapy

-Gleason score ≥ 6 ,

-increasing levels of PSA and PSA doubling time (DT) ≤ 6 months.

-Informed

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	prostate cancer relapse group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	$^{64}\text{CuCl}_2$
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

6,7 mCi millicurie(s)

Number of subjects in period 1	prostate cancer relapse group
Started	50
Completed	50

Baseline characteristics

End points

End points reporting groups

Reporting group title	prostate cancer relapse group
Reporting group description: -	
Subject analysis set title	diagnostic accuracy
Subject analysis set type	Full analysis
Subject analysis set description:	
PCapatient with biochemical relapse after surgery or external-beam radiation therapy	

Primary: detection rate (DR) of $^{64}\text{CuCl}_2$ PET/CT

End point title	detection rate (DR) of $^{64}\text{CuCl}_2$ PET/CT ^[1]
End point description:	

End point type	Primary
End point timeframe:	
Time frame: From February to October 2016	

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: DRs were calculated as the ratio between the number of positive patients (or lesions in the case of lesion-based analysis) and the total number of patients enrolled (or lesions).

End point values	diagnostic accuracy			
Subject group type	Subject analysis set			
Number of subjects analysed	50			
Units: percentage	41			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

The adverse event will be notified to the Galliera pharmacovigilance contact person within 24 hours from when the principal investigator became aware of it and that subsequent relevant information will be communicated within eight days of the first report

Adverse event reporting additional description:

No adverse events were observed.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18
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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: Adverse Events

No drug-related pharmacologic effects or physiologic responses occurred. No adverse reactions were observed after the injection

of $^{64}\text{CuCl}_2$. All observed parameters (i.e., blood pressure, heart rate, body temperature) remained normal and unchanged during

and after the examination. No patient reported subjective symptoms.

In addition, no modification of the above-mentioned blood tests was reported 10 d after $^{64}\text{CuCl}_2$ injection.

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