Clinical trial results:
ASSESSMENT OF MULTIDRUG RESISTANCE IN BREAST CANCER AND LOW GRADE GLIOMA PATIENTS WITH [11C]TARIQUIDAR PET. A PILOT STUDY

Summary

EudraCT number	2011-004189-13
Trial protocol	AT
Global end of trial date	31 August 2016

Results information

Result version number	v1 (current)
This version publication date	21 September 2019
First version publication date	21 September 2019

Trial information

Trial identification

Sponsor protocol code	1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgsse 23, Viena, Austria, 1090
Public contact	Department of Clinical Pharmacology, Medizinische Universität wien, 0043 1404002981, klin-pharmakologie@meduniwien.ac.at
Scientific contact	Department of Clinical Pharmacology, Medizinische Universität wien, 0043 1404002981, klin-pharmakologie@meduniwien.ac.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	30 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 August 2016
Global end of trial reached?	Yes
Global end of trial date	31 August 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To correlate PET imaging outcome parameters (e.g. volume of distribution (VT) of [11C]tariquidar in tumor tissue) at staging with Pgp expression levels measured by IHC and/or at baseline (diagnostic biopsy)

Protection of trial subjects:

Subjects were during the trail under the supervision of a physician or an experienced Nurse.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 January 2012
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: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited by use of data base of the Dep. of Clinical Pharmacology, Medical University of Vienna.

Pre-assignment

Screening details:

Check of the in- and exclusion criteria, physical examination, vital signs, laboratory assessment

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group B, Breast cancer

Arm description: -

Arm type	Experimental
Investigational medicinal product name	[11C]tariquidar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

60 min, total effective dose <3 mSv for an i.v. injected activity amount of 400 MBq.

Arm title	Group G, Glioma

Arm description: -

Arm type	Experimental
Investigational medicinal product name	[11C]tariquidar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

60 min, total effective dose <3 mSv for an i.v. injected activity amount of 400 MBq.

Number of subjects in period 1	Group B, Breast cancer	Group G, Glioma
Started	1	6
Completed	1	6

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	7	7	
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)	7	7	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	4	4	
Male	3	3	

End points

End points reporting groups

Reporting group title	Group B, Breast cancer
Reporting group description: -	
Reporting group title	Group G, Glioma
Reporting group description: -	

Primary: Correlation of [11C]tariquidar PET imaging outcome parameters at staging with

End point title	Correlation of [11C]tariquidar PET imaging outcome parameters at staging with[1]
End point description:	
End point type	Primary
End point timeframe:	
60 min	

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 unsuccessful recruitment not enough subjects were involved in the study in order to make a statistical analysis.

End point values	Group B, Breast cancer	Group G, Glioma		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	6		
Units: volume of distribution				
number (not applicable)	1	6		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 03.10.2013-31.08.2016	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0
Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)		
Nervous system disorders			
Word finding difficulty			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Dysgeusia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Social circumstances			
Fasting	Additional description: Dizziness, Nausea		

subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1		
Infections and infestations Cold sore subjects affected / exposed occurrences (all)	 1 / 7 (14.29%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 October 2015	Change in study protocol, cover letter and patient information letter
15 December 2015	Change in patient information letter, study protocol

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
31 August 2016	Unsuccessful recruitment	-

Notes:

Limitations and caveats

None reported