

**Clinical trial results:****Proteinuria in patients with bevacizumab (Avastin®): Identification of potential protein biomarker candidates for monitoring treatment side-effects****Summary**

EudraCT number	2009-010857-10
Trial protocol	AT
Global end of trial date	28 February 2014

Results information

Result version number	v1 (current)
This version publication date	28 May 2017
First version publication date	28 May 2017

Trial information**Trial identification**

Sponsor protocol code	BEV-PROT-001
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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	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Medical University of Vienna, Medical University of Vienna, +43 1 40400 32320, andreas.peyrl@meduniwien.ac.at
Scientific contact	Medical University of Vienna, Medical University of Vienna, +43 1 40400 32320, andreas.peyrl@meduniwien.ac.at
Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Department of Pediatrics, Medical University of Vienna, +43 14040032320, andreas.peyrl@meduniwien.ac.at
Scientific contact	Department of Pediatrics, Medical University of Vienna, +43 14040032320, andreas.peyrl@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	28 February 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 February 2014
Global end of trial reached?	Yes
Global end of trial date	28 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Identification of potential biomarker proteins that (may) appear during bevacizumab therapy

Protection of trial subjects:

Collection of urine, no pain or stress expected

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 May 2009
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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	7
Adolescents (12-17 years)	8
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Pediatric patients receiving bevacizumab for therapeutic reasons

Pre-assignment

Screening details:

Pediatric patients receiving bevacizumab for therapeutic reasons

Pre-assignment period milestones

Number of subjects started	15
Intermediate milestone: Number of subjects	Receiving bevacizumab: 15
Number of subjects completed	15

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	Arm 1
Arm description: Patients receiving bevacizumab	
Arm type	Arm 1
Investigational medicinal product name	Bevacizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous drip use

Dosage and administration details:

10mg/kg every second week

Number of subjects in period 1	Arm 1
Started	15
Completed	15

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)
Reporting group description:	
Overall trial	

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	15	15	
Age categorical			
Pediatric patients receiving bevacizumab			
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)	7	7	
Adolescents (12-17 years)	8	8	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	8	8	
Male	7	7	

Subject analysis sets

Subject analysis set title	Overall trial
Subject analysis set type	Full analysis
Subject analysis set description:	
Overall trial	

Reporting group values	Overall trial		
Number of subjects	15		
Age categorical			
Pediatric patients receiving bevacizumab			
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)	7		
Adolescents (12-17 years)	8		
Adults (18-64 years)	0		
From 65-84 years	0		

85 years and over	0		
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Gender categorical Units: Subjects			
Female	8		
Male	7		

End points

End points reporting groups

Reporting group title	Arm 1
Reporting group description:	
Patients receiving bevacizumab	
Subject analysis set title	Overall trial
Subject analysis set type	Full analysis
Subject analysis set description:	
Overall trial	

Primary: Arm 1

End point title	Arm 1
End point description:	
End point type	Primary
End point timeframe:	
2 weeks	

End point values	Arm 1	Overall trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	15	15		
Units: Spots	15	15		

Statistical analyses

Statistical analysis title	Mean +/- standard deviation
Comparison groups	Arm 1 v Overall trial
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Mean +/- standard deviation
Parameter estimate	Mean difference (final values)
Variability estimate	Standard deviation

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

2 weeks

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (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	0 / 15 (0.00%)		

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 occurred

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.

We could not identify any potential protein biomarker candidates.

Notes: