



Clinical trial results:

Cerebrospinal fluid (CSF) and plasma pharmacokinetics of liposomal cytarabine (DepoCyte®) after intrathecal administration in children with malignant brain tumors and leptomeningeal dissemination

Summary

EudraCT number	2006-004982-32
Trial protocol	AT
Global end of trial date	23 October 2013

Results information

Result version number	v1 (current)
This version publication date	28 February 2016
First version publication date	28 February 2016

Trial information

Trial identification

Sponsor protocol code	LIPDEP-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 14040032320, andreas.peyrl@meduniwien.ac.at
Scientific contact	Medical University of Vienna, 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	23 October 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

CSF: AUC, t1/2, Cmax, Cmin, Cav(ss)

Protection of trial subjects:

Using an Ommaya reservoir for CSF sampling

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 December 2006
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	2
Children (2-11 years)	11
Adolescents (12-17 years)	6
Adults (18-64 years)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Pediatric patients with a malignant CNS tumor and leptomeningeal dissemination or risk of leptomeningeal dissemination

Pre-assignment

Screening details:

Pediatric patients with a malignant CNS tumor and leptomeningeal dissemination or risk of leptomeningeal dissemination

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

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: -	
Arm type	Arm 1
Investigational medicinal product name	Liposomal cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intraventricular use

Dosage and administration details:

25-50mg intraventricular

Number of subjects in period 1	Arm 1
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	20	20	
Age categorical			
Units: Subjects			
Infants and toddlers (28 days-23 months)	2	2	
Children (2-11 years)	11	11	
Adolescents (12-17 years)	6	6	
Adults (18-64 years)	1	1	
Gender categorical			
Units: Subjects			
Female	9	9	
Male	11	11	

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	20		
Age categorical			
Units: Subjects			
Infants and toddlers (28 days-23 months)	2		
Children (2-11 years)	11		
Adolescents (12-17 years)	6		
Adults (18-64 years)	1		
Gender categorical			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Arm 1
Reporting group description: -	
Subject analysis set title	Overall trial
Subject analysis set type	Full analysis
Subject analysis set description:	
Overall trial	

Primary: CSF concentration of liposomal cytarabine

End point title	CSF concentration of liposomal cytarabine
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	20	20		
Units: mg/l				
number (not applicable)				
Overall trial	20	20		

Statistical analyses

Statistical analysis title	Mean +/- standard deviation
Comparison groups	Arm 1 v Overall trial
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Mean +/- Standard deviation
Parameter estimate	Mean difference (final values)
Confidence interval	
Variability estimate	Standard deviation

Adverse events

Adverse events information

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 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 20 (5.00%)		
Nervous system disorders			
headache			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 February 2010	In the different age groups with different dosing, the number of patients that have been recruited varied. To get reasonable pharmacokinetics values in the different age groups, recruitment of additional patients was necessary.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/19492871>

<http://www.ncbi.nlm.nih.gov/pubmed/24129691>