Clinical trial results:
Etude prospective multicentrique de phase II évaluant l'adjonction du rituximab et du DepoCyte® en intrathécal au protocole de chimiothérapie C5R chez les patients âgés de 18 à 60 ans porteurs de lymphomes non hodgkiniens cérébraux primitifs et de lymphomes systémiques diffus à grandes cellules B avec envahissement neuro-méningé au diagnostic.

Summary

EudraCT number	2006-000454-44
Trial protocol	FR BE
Global end of trial date	16 March 2017

Results information

Result version number	v1 (current)
This version publication date	19 May 2019
First version publication date	19 May 2019

Trial information

Trial identification

Sponsor protocol code	R-C5R 2006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00553943
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	LYSA
Sponsor organisation address	CHU LYON SUD, PIERRE BENITE, France,
Public contact	PROJECT MANAGEMENT, LYSARC, affaires-reglementaires@lysarc.org
Scientific contact	COORDINATING INVESTIGATOR, LYSA, herve.ghesquieres@chu-lyon.fr

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	16 March 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To measure the rate of complete response (CR and UCR) at the end of a course of immuno-chemotherapy:
-before cerebral radiotherapy for PCL
-after the course of immuno-chemotherapy for aggressive lymphomas with neuromeningeal involvement

Protection of trial subjects:

Standard care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 August 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 12
Country: Number of subjects enrolled	France: 48
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	29
From 65 to 84 years	31

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

clinical examination (weight, BSA, pulse, blood pressure, Temp, physical examination, ECOG PS, Biochemical test, blood celle count), inclusion/exclusion criteria

Period 1

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

Arms

Arm title	Brain Lymphoma

Arm description: -

Arm type	Experimental
Investigational medicinal product name	cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intrathecal use

Dosage and administration details:

2 cycles of R-COPADEM, followed by 2 cycles of R-CYM

Cytarabine : 50 mg on D3 of each cycle

Number of subjects in period 1	Brain Lymphoma
Started	60
Completed	53
Not completed	7
No treatment received	1
Protocol deviation	6

Baseline characteristics

End points

End points reporting groups

Reporting group title	Brain Lymphoma

Reporting group description: -

Primary: Complete response rate

End point title	Complete response rate[1]

End point description:

End point type	Primary

End point timeframe:

End of chemotherapy

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: One arm = no comparative analysis

End point values	Brain Lymphoma			
Subject group type	Reporting group			
Number of subjects analysed	53			
Units: percent				
arithmetic mean (confidence interval 5%)	66 (53.3 to 78.8)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From consent signature until one month after end of treatment or early discontinuation

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16

Reporting groups

Reporting group title	Experimental

Reporting group description: -

Serious adverse events	Experimental		
Total subjects affected by serious adverse events			
subjects affected / exposed	31 / 54 (57.41%)		
number of deaths (all causes)	16		
number of deaths resulting from adverse events	5		
Vascular disorders			
VASCULAR DISORDERS			
subjects affected / exposed	3 / 54 (5.56%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
CARDIAC DISORDERS			
subjects affected / exposed	1 / 54 (1.85%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
NERVOUS SYSTEM DISORDERS			
subjects affected / exposed	3 / 54 (5.56%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
BLOOD AND LYMPHATIC SYSTEM DISORDERS			

subjects affected / exposed	3 / 54 (5.56%)		
occurrences causally related to treatment / all	5 / 5		
deaths causally related to treatment / all	1 / 1		
General disorders and administration site conditions			
BLOOD AND LYMPHATIC SYSTEM DISORDERS			
subjects affected / exposed	3 / 54 (5.56%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
GASTROINTESTINAL DISORDERS			
subjects affected / exposed	1 / 54 (1.85%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			
subjects affected / exposed	1 / 54 (1.85%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
PSYCHIATRIC DISORDERS			
subjects affected / exposed	3 / 54 (5.56%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
RENAL AND URINARY DISORDERS			
subjects affected / exposed	4 / 54 (7.41%)		
occurrences causally related to treatment / all	3 / 4		
deaths causally related to treatment / all	1 / 1		
Infections and infestations			
INFECTIONS AND INFESTATIONS			
subjects affected / exposed	25 / 54 (46.30%)		
occurrences causally related to treatment / all	28 / 36		
deaths causally related to treatment / all	3 / 3		
Metabolism and nutrition disorders			

METABOLISM AND NUTRITION DISORDERS			
subjects affected / exposed	2 / 54 (3.70%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Experimental		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 54 (98.15%)		
Vascular disorders			
VASCULAR DISORDERS			
subjects affected / exposed	3 / 54 (5.56%)		
occurrences (all)	3		
General disorders and administration site conditions			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
subjects affected / exposed	11 / 54 (20.37%)		
occurrences (all)	16		
Respiratory, thoracic and mediastinal disorders			
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			
subjects affected / exposed	2 / 54 (3.70%)		
occurrences (all)	2		
Psychiatric disorders			
PSYCHIATRIC DISORDERS			
subjects affected / exposed	4 / 54 (7.41%)		
occurrences (all)	4		
Investigations			
INVESTIGATIONS			
subjects affected / exposed	7 / 54 (12.96%)		
occurrences (all)	8		
Cardiac disorders			
CARDIAC DISORDERS			
subjects affected / exposed	1 / 54 (1.85%)		
occurrences (all)	1		
Nervous system disorders			

NERVOUS SYSTEM DISORDERS subjects affected / exposed occurrences (all)	6 / 54 (11.11%) 6		
Blood and lymphatic system disorders BLOOD AND LYMPHATIC SYSTEM DISORDERS subjects affected / exposed occurrences (all)	52 / 54 (96.30%) 400		
Gastrointestinal disorders GASTROINTESTINAL DISORDERS subjects affected / exposed occurrences (all)	7 / 54 (12.96%) 7		
Hepatobiliary disorders HEPATOBILIARY DISORDERS subjects affected / exposed occurrences (all)	3 / 54 (5.56%) 4		
Renal and urinary disorders RENAL AND URINARY DISORDERS subjects affected / exposed occurrences (all)	6 / 54 (11.11%) 6		
Infections and infestations INFECTIONS AND INFESTATIONS subjects affected / exposed occurrences (all)	38 / 54 (70.37%) 68		
Metabolism and nutrition disorders METABOLISM AND NUTRITION DISORDERS subjects affected / exposed occurrences (all)	6 / 54 (11.11%) 9		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 January 2011	Stop of Arm 2 due to lack of enrollment

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
12 January 2011	Stop of Arm 2 due to lack of enrollment	-

Notes:

Limitations and caveats

None reported