



Clinical trial results:

A randomized, double-blind, multi-center, multi-national Phase III trial to compare efficacy and safety of BI 695500 plus chemotherapy versus rituximab plus chemotherapy in patients with untreated follicular non-Hodgkin's lymphoma.

Summary

EudraCT number	2011-002908-33
Trial protocol	GB BE CZ IT SK
Global end of trial date	19 October 2012

Results information

Result version number	v1 (current)
This version publication date	08 July 2018
First version publication date	08 July 2018
Summary attachment (see zip file)	Statement (1301.2_Statement_Eudract.pdf)

Trial information

Trial identification

Sponsor protocol code	1301.2
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 8002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 8002430127, clintriage.rdg@boehringer-ingelheim.com

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	19 October 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 October 2012
Global end of trial reached?	Yes
Global end of trial date	19 October 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to compare the efficacy (best overall response rate after completion of induction therapy) of BI 695500 plus chemotherapy versus rituximab plus chemotherapy in patients with untreated follicular lymphoma

Protection of trial subjects:

No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2012
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	Netherlands: 99999
Country: Number of subjects enrolled	Slovakia: 99999
Worldwide total number of subjects	199998
EEA total number of subjects	199998

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)	99999
From 65 to 84 years	99999
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

Pre-assignment

Screening details:

All subjects had to be screened for eligibility to participate in the trial. Subjects had to attend specialist sites which would then ensure that they (the subjects) met all inclusion/exclusion criteria. Subjects were not to be randomised to trial treatment if any one of the specific entry criteria were violated.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

As this is a double-blind trial, patients, investigators and all blinded trial personnel should remain blinded with regard to the randomized treatment assignments until after the final database lock.

Arms

Are arms mutually exclusive?	Yes
Arm title	BI 695500

Arm description:

BI 695500 (intravenous infusion) plus cyclophosphamide, doxorubicin, vincristine and prednisone/prednisolone or its equivalent glucocorticoid (CHOP), cyclophosphamide, vincristine and prednisone/prednisolone or its equivalent glucocorticoid (CVP) or bendamustine chemotherapy
BI 695500:

- 375 mg/m² every 3 weeks for six cycles, for those patients receiving CHOP or CVP.
- 375 mg/m² every 4 weeks for six cycles, for those patients receiving bendamustine.
- 375 mg/m² every 8 weeks (12 infusions during the 2 years maintenance)

Arm type	Experimental
Investigational medicinal product name	BI 695500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BI 695500 plus cyclophosphamide, doxorubicin, vincristine and prednisone/prednisolone or its equivalent glucocorticoid (CHOP), cyclophosphamide, vincristine and prednisone/prednisolone or its equivalent glucocorticoid (CVP) or bendamustine chemotherapy BI 695500:

- 375 mg/m² every 3 weeks for six cycles, for those patients receiving CHOP or CVP.
- 375 mg/m² every 4 weeks for six cycles, for those patients receiving bendamustine.
- 375 mg/m² every 8 weeks (12 infusions during the 2 years maintenance)

Arm title	Rituximab
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Arm description:

Rituximab (Rituxan®) plus CHOP, CVP or bendamustine chemotherapy Rituximab:

- 375 mg/m² every 3 weeks for six cycles, for those patients receiving CHOP or CVP.
- 375 mg/m² every 4 weeks for six cycles, for those patients receiving bendamustine.
- 375 mg/m² every 8 weeks (12 infusions during the 2 years maintenance)

Arm type	Active comparator
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Investigational medicinal product name	Rituximab (Rituxan®)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Rituximab (Rituxan®) plus CHOP, CVP or bendamustine chemotherapy

Rituximab:

- 375 mg/m² every 3 weeks for six cycles, for those patients receiving CHOP or CVP.
- 375 mg/m² every 4 weeks for six cycles, for those patients receiving bendamustine.
- 375 mg/m² every 8 weeks (12 infusions during the 2 years maintenance)

Number of subjects in period 1	BI 695500	Rituximab
Started	99999	99999
Completed	99999	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial
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Reporting group description:

This is a Phase III, randomized, double-blind, parallel arm, active comparator trial.

No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

Reporting group values	Overall Trial	Total	
Number of subjects	199998	199998	
Age categorical			
Units: Subjects			

Age continuous			
No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
No patient entered the study, therefore no results data available. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.			
Units: Subjects			
Female	99999	99999	
Male	99999	99999	

End points

End points reporting groups

Reporting group title	BI 695500
Reporting group description:	
BI 695500 (intravenous infusion) plus cyclophosphamide, doxorubicin, vincristine and prednisone/prednisolone or its equivalent glucocorticoid (CHOP), cyclophosphamide, vincristine and prednisone/prednisolone or its equivalent glucocorticoid (CVP) or bendamustine chemotherapy	
BI 695500:	
- 375 mg/m ² every 3 weeks for six cycles, for those patients receiving CHOP or CVP.	
- 375 mg/m ² every 4 weeks for six cycles, for those patients receiving bendamustine.	
- 375 mg/m ² every 8 weeks (12 infusions during the 2 years maintenance)	
Reporting group title	Rituximab
Reporting group description:	
Rituximab (Rituxan®) plus CHOP, CVP or bendamustine chemotherapy	
Rituximab:	
- 375 mg/m ² every 3 weeks for six cycles, for those patients receiving CHOP or CVP.	
- 375 mg/m ² every 4 weeks for six cycles, for those patients receiving bendamustine.	
- 375 mg/m ² every 8 weeks (12 infusions during the 2 years maintenance)	

Primary: Objective response (OR) (complete response [CR] + partial response [PR]) at the completion of induction therapy, as defined by the modified International Working Group (IWG) criteria 2007, using Independent Radiology Assessment.

End point title	Objective response (OR) (complete response [CR] + partial response [PR]) at the completion of induction therapy, as defined by the modified International Working Group (IWG) criteria 2007, using Independent Radiology Assessment. ^[1]
End point description:	
Objective response (OR) (complete response [CR] + partial response [PR]) at the completion of induction therapy, as defined by the modified International Working Group (IWG) criteria 2007, using Independent Radiology Assessment is presented.	
99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.	
The primary analysis set will be the full analysis set (FAS) according to the intention-to-treat principle. The FAS consists of all randomized patients who received at least one dose of trial drug and had a baseline tumor assessment	
End point type	Primary
End point timeframe:	
up to 24 weeks of induction immunochemotherapy.	

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: No subjects were enrolled in the trial hence results are not available

End point values	BI 695500	Rituximab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99999 ^[2]	99999 ^[3]		
Units: percentage of participants	99999	99999		

Notes:

[2] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[3] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Secondary: Time to treatment failure

End point title	Time to treatment failure
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End point description:

Time to treatment failure is defined as the time from randomization until treatment failure including discontinuation of treatment for any reason (e.g., disease progression/relapse, treatment toxicity, patient preference, initiation of new anti-lymphoma treatment or death). Per protocol planned end of induction/maintenance treatment is not regarded as treatment failure. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Secondary
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End point timeframe:

up to 24 weeks of induction immunochemotherapy

End point values	BI 695500	Rituximab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99999 ^[4]	99999 ^[5]		
Units: months				
arithmetic mean (standard deviation)	0 (± 0)	0 (± 0)		

Notes:

[4] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[5] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival (PFS)

End point title	Progression-free survival (PFS)
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End point description:

Progression-free survival (PFS) will be assessed based on the investigator assessment of response. Progression-free survival is defined as the time from randomization until disease progression/relapse or death by any cause, whichever occurs first. Disease progression/relapse is assessed according to the modified IWG response criteria for malignant lymphoma 2007. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Secondary
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End point timeframe:

up to 24 weeks of induction immunochemotherapy

End point values	BI 695500	Rituximab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99999 ^[6]	99999 ^[7]		
Units: months				
arithmetic mean (standard deviation)	0 (± 0)	0 (± 0)		

Notes:

[6] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[7] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival
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End point description:

Overall survival is defined as the time from randomization until death as a result of any cause. 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Secondary
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End point timeframe:

time from randomization until death as a result of any cause; collected up to database lock date

End point values	BI 695500	Rituximab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99999 ^[8]	99999 ^[9]		
Units: months				
arithmetic mean (standard deviation)	0 (± 0)	0 (± 0)		

Notes:

[8] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

[9] - No patient entered the study, therefore no results data available. 99999 is "Not applicable" value

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

All Adverse events occurring during the course of the clinical trial (which begins with signing of informed consent and ends with the end of the Residual Effect Period [REP]); up to 2 years

Adverse event reporting additional description:

No patient entered the study, therefore no results data available.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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Frequency threshold for reporting non-serious adverse events: 5 %

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 subjects were enrolled in the trial hence results are not available

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.

Discontinued by Boehringer Ingelheim during preparation of the trial. No patient entered the study, therefore no results data are available

Notes: