



Clinical trial results:

Randomized phase II study of treatment with R-CHOP vs Bortezomib-R-CAP for young patients with poor IPI diffuse large B-cell lymphoma.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-005138-12 |
| Trial protocol | ES |
| Global end of trial date | 08 August 2018 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 03 July 2021 |
| First version publication date | 03 July 2021 |
| Summary attachment (see zip file) | BR-CAP (BRCAP-GELTAMO12_Clinical_Study_Report_FINAL.pdf) |

Trial information

Trial identification

| | |
|-----------------------|-----------------|
| Sponsor protocol code | BRCAP-GELTAMO12 |
|-----------------------|-----------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GELTAMO |
| Sponsor organisation address | H. MARQUES DE VALDECILLA SERVICIO DE HEMATOLOGIA, SANTANDER, Spain, 39008 |
| Public contact | GELTAMO, Grupo Español de Linfomas y Trasplante Autólogo de Médula Ósea, 0034 913195780NA, dm@geltamo.com |
| Scientific contact | GELTAMO, Grupo Español de Linfomas y Trasplante Autólogo de Médula Ósea, 0034 913195780NA, sc@geltamo.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 | 08 August 2018 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 08 August 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the proportion of patients with event-free survival at 2 years in patients diagnosed of DLBCL with aIPI > 1 or aIPI=1 with elevated levels of beta 2-microglobulin (above UNL).
UNL= Upper Normal Limit.

Protection of trial subjects:

Once trial treatment is initiated, pre-treatment visits will be conducted at the start of each cycle, weekly visits at 60 days after the end of the 6 treatment cycles, and follow-up visits every 3 months after the end of the 6 treatment cycles.
safety visits 60 days after the end of the 6 treatment cycles and follow-up visits every 3 months for the first 2 years and every 6 months until the 5th year.
2 years and every 6 months until the 5th year.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 29 March 2013 |
| 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 | Spain: 121 |
| Worldwide total number of subjects | 121 |
| EEA total number of subjects | 121 |

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) | 121 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Authorisation 26/03/2013, Start of rehearsal 03/10/2013, First Patient Inclusion 03/10/2013, End of recruitment 17/02/2016, End of trial in Spain 08/08/2018

Pre-assignment

Screening details:

Patients diagnosed with primary diffuse DLBCL

2.- Age between 18 and 70 years.

3.- Age adjusted IPI higher than 1 or equal 1, with high levels of beta-2-microglobulin (above UNL)

4.- Neoplastic B lymphocytes for CD20 positivity.

5.- ECOG 0-3 6.- More than 12 weeks of life expectancy.

7.- Signed Informed Consent.

Pre-assignment period milestones

| | |
|----------------------------|-----|
| Number of subjects started | 121 |
|----------------------------|-----|

| | |
|------------------------------|-----|
| Number of subjects completed | 121 |
|------------------------------|-----|

Period 1

| | |
|----------------|--------------------------------|
| Period 1 title | OVERALL TRIAL (overall period) |
|----------------|--------------------------------|

| | |
|------------------------------|-----|
| Is this the baseline period? | Yes |
|------------------------------|-----|

| | |
|-------------------|-----------------------------|
| Allocation method | Non-randomised - controlled |
|-------------------|-----------------------------|

| | |
|---------------|-------------|
| Blinding used | Not blinded |
|---------------|-------------|

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|-----------|-----------------------------|
| Arm title | EXPERIMENTAL ARM BR-CAP21X2 |
|-----------|-----------------------------|

Arm description:

Six cycles of treatment with bortezomib were administered subcutaneously at a dose of 1.3 mg/m² on days 1, 8, and 15, followed by rituximab iv at a dose of 375 mg/m² on day 1 followed by chemotherapy: cyclophosphamide 750 mg/m² iv on day 1 + Adriamycin 50 mg/m² iv on day 1 + prednisone 100 mg oral on days 1-5. The cycles were administered every 21 days

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|------------|
| Investigational medicinal product name | BORTEZOMIB |
|--|------------|

| | |
|--|------|
| Investigational medicinal product code | PR-1 |
|--|------|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|--|
| Pharmaceutical forms | Powder and solvent for solution for injection in cartridge |
|----------------------|--|

| | |
|--------------------------|-----------|
| Routes of administration | Injection |
|--------------------------|-----------|

Dosage and administration details:

6 cycles administered every 21 days. Bortezomib will be administered on days 1-8-15.
1.3 mg/m² sc.

| | |
|--|-----------|
| Investigational medicinal product name | RITUXIMAB |
|--|-----------|

| | |
|--|------|
| Investigational medicinal product code | PR-6 |
|--|------|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|---------------------------------------|
| Pharmaceutical forms | Concentrate for solution for infusion |
|----------------------|---------------------------------------|

| | |
|--------------------------|---------------------------------------|
| Routes of administration | Concentrate for solution for infusion |
|--------------------------|---------------------------------------|

Dosage and administration details:

(Comparator) 6 cycles administered every 21 days. Rituximab will be administered on day 1.
375 mg/m² iv.

| | |
|--|---------------------------------|
| Investigational medicinal product name | CYCLOPHOSPHAMIDE |
| Investigational medicinal product code | PR-3 |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Solution for injection |

Dosage and administration details:

6 cycles administered every 21 days. Cyclophosphamide will be administered on day 1.
750 mg/m² iv.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | ADRIAMYCIN |
| Investigational medicinal product code | PR-8 |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Concentrate for solution for infusion |

Dosage and administration details:

6 treatment cycles administered every 21 days. Adriamycin to be administered on day 1
50 mg/m² iv.

| | |
|--|------------|
| Investigational medicinal product name | PREDNISONE |
| Investigational medicinal product code | PR-5 |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

6 cycles administered every 21 days. Prednisone will be administered on days 1 to 5.
100 mg oral.

| | |
|------------------|------------------------|
| Arm title | CONTROL ARM R-CHOP21X2 |
|------------------|------------------------|

Arm description:

Six cycles of treatment with R-CHOP were administered: Rituximab 375 mg/m² iv on day 1 followed by CHOP-type chemotherapy (cyclophosphamide 750 mg/m² iv on day 1 + Adriamycin 50 mg/m² iv on day 1 + vincristine 1.4 mg/m² iv (maximum 2 mg) on day 1 + prednisone 100 mg oral on days 1-5). The cycles were administered every 21 days.

The administration of rituximab was performed as an iv infusion. The first infusion was started at a rate of 50 mg/hour, and after the first 30 minutes, the dose could be increased in increments of 50 mg/hour every 30 minutes up to a maximum of 400 mg/hour. Subsequent infusions could be administered at an initial rate of 100 mg/hour and increased by 100 mg/hour at intervals of 30 minutes to a maximum of 400 mg/hour.

| | |
|--|---------------------------------------|
| Arm type | Control arm |
| Investigational medicinal product name | RITUXIMAB |
| Investigational medicinal product code | PR-6 |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Concentrate for solution for infusion |

Dosage and administration details:

(Comparator) 6 cycles administered every 21 days. Rituximab will be administered on day 1.
Dose/route of administration: 375 mg/m² iv.

| | |
|--|---------------------------------|
| Investigational medicinal product name | CYCLOPHOSPHAMIDE |
| Investigational medicinal product code | PR-3 |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Solution for injection |

Dosage and administration details:

6 cycles administered every 21 days. Cyclophosphamide will be administered on day 1.

Dose/route of administration: 750 mg/m² iv.

| | |
|--|------------|
| Investigational medicinal product name | PREDNISONE |
| Investigational medicinal product code | PR-5 |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

6 cycles administered every 21 days. Prednisone will be administered on days 1 to 5.

Dose/route of administration: 100 mg oral.

| | |
|--|---------------------------------|
| Investigational medicinal product name | VINCRISTINE |
| Investigational medicinal product code | PR-10 |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Solution for injection |

Dosage and administration details:

6 treatment cycles administered every 21 days

1.4 mg/m² iv

| Number of subjects in period 1 | EXPERIMENTAL ARM BR-CAP21X2 | CONTROL ARM R- CHOP21X2 |
|---------------------------------------|--------------------------------|----------------------------|
| Started | 60 | 61 |
| Completed | 60 | 61 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | OVERALL TRIAL |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values | OVERALL TRIAL | Total | |
|--|---------------|-------|--|
| Number of subjects | 121 | 121 | |
| 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) | 100 | 100 | |
| From 65-84 years | 21 | 21 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 60 | 60 | |
| Male | 61 | 61 | |

Subject analysis sets

| | |
|----------------------------|--------------------|
| Subject analysis set title | Inclusion criteria |
|----------------------------|--------------------|

| | |
|---------------------------|---------------|
| Subject analysis set type | Full analysis |
|---------------------------|---------------|

Subject analysis set description:

- Patients diagnosed with primary diffuse DLBCL who have never received treatment for this condition.

2.- Age between 18 and 70 years.

3.- Age adjusted IPI higher than 1 or equal 1, with high levels of beta-2-microglobulin (above UNL)

4.- Neoplastic B lymphocytes for CD20 positivity.

5.- ECOG 0-3 6.- More than 12 weeks of life expectancy.

7.- Signed Informed Consent.

8.- Nor pregnant women nor breast-feeding women without heterosexual activity during the entire study. Women with

heterosexual activity only if they are willing to use two methods of contraceptive. The two contraceptive methods can

be, two barrier method or a barrier method combined with an hormonal contraceptive method to prevent

pregnancy, used during the entire study and until 3 months after the study completion.

| | |
|----------------------------|--------------------|
| Subject analysis set title | Exclusion criteria |
|----------------------------|--------------------|

| | |
|---------------------------|---------------|
| Subject analysis set type | Full analysis |
|---------------------------|---------------|

Subject analysis set description:

. Pregnant women or in breast-feeding period, or adults in childbearing period not using an effective contraception

method. 2. Patients with CNS lymphoma 3. Patients with severe impairment of renal function (creatinine > 2.5 UNL)

or hepatic (bilirubin or ALT / AST > 3 UNL), unless it is suspected to be due to the disease. 4. HIV positive patients 5.

Patient previously treated for the DLBCL 6. Positive determination of chronic hepatitis B (defined as

positive serology
for HBsAg). It will be allowed to enroll patients with hidden or previous hepatitis (defined as positive
antibodies
against the core of the hepatitis B virus [HBcAb] and HBsAg negative) if undetectable HBV DNA. 7.
Positive results
for hepatitis C (antibody serology for hepatitis C virus [HCV]). Patients with HCV positive may
participate only if the
result of the PCR is negative for HCV RNA. 8. Patients with previous history of cardiac disease:
ventricular ejection
fraction < 50%. 9.

| Reporting group values | Inclusion criteria | Exclusion criteria | |
|---|---------------------------------------|---------------------------------------|--|
| Number of subjects | 121 | 121 | |
| Age categorical Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over | 100 21 | 100 21 | |
| Gender categorical Units: Subjects | | | |
| Female | 60 | 60 | |
| Male | 61 | 61 | |

End points

End points reporting groups

| | |
|-----------------------|-----------------------------|
| Reporting group title | EXPERIMENTAL ARM BR-CAP21X2 |
|-----------------------|-----------------------------|

Reporting group description:

Six cycles of treatment with bortezomib were administered subcutaneously at a dose of 1.3 mg/m² on days 1, 8, and 15, followed by rituximab iv at a dose of 375 mg/m² on day 1 followed by chemotherapy: cyclophosphamide 750 mg/m² iv on day 1 + Adriamycin 50 mg/m² iv on day 1 + prednisone 100 mg oral on days 1-5. The cycles were administered every 21 days

| | |
|-----------------------|------------------------|
| Reporting group title | CONTROL ARM R-CHOP21X2 |
|-----------------------|------------------------|

Reporting group description:

Six cycles of treatment with R-CHOP were administered: Rituximab 375 mg/m² iv on day 1 followed by CHOP-type chemotherapy (cyclophosphamide 750 mg/m² iv on day 1 + Adriamycin 50 mg/m² iv on day 1 + vincristine 1.4 mg/m² iv (maximum 2 mg) on day 1 + prednisone 100 mg oral on days 1-5). The cycles were administered every 21 days.

The administration of rituximab was performed as an iv infusion. The first infusion was started at a rate of 50 mg/hour, and after the first 30 minutes, the dose could be increased in increments of 50 mg/hour every 30 minutes up to a maximum of 400 mg/hour. Subsequent infusions could be administered at an initial rate of 100 mg/hour and increased by 100 mg/hour at intervals of 30 minutes to a maximum of 400 mg/hour.

| | |
|----------------------------|--------------------|
| Subject analysis set title | Inclusion criteria |
|----------------------------|--------------------|

| | |
|---------------------------|---------------|
| Subject analysis set type | Full analysis |
|---------------------------|---------------|

Subject analysis set description:

- Patients diagnosed with primary diffuse DLBCL who have never received treatment for this condition.
2.- Age between 18 and 70 years.
3.- Age adjusted IPI higher than 1 or equal 1, with high levels of beta-2-microglobulin (above UNL)
4.- Neoplastic B lymphocytes for CD20 positivity.
5.- ECOG 0-3 6.- More than 12 weeks of life expectancy.
7.- Signed Informed Consent.
8.- Nor pregnant women nor breast-feeding women without heterosexual activity during the entire study. Women with heterosexual activity only if they are willing to use two methods of contraceptive. The two contraceptive methods can be, two barrier method or a barrier method combined with an hormonal contraceptive method to prevent pregnancy, used during the entire study and until 3 months after the study completion.

| | |
|----------------------------|--------------------|
| Subject analysis set title | Exclusion criteria |
|----------------------------|--------------------|

| | |
|---------------------------|---------------|
| Subject analysis set type | Full analysis |
|---------------------------|---------------|

Subject analysis set description:

1. Pregnant women or in breast-feeding period, or adults in childbearing period not using an effective contraception method. 2. Patients with CNS lymphoma 3. Patients with severe impairment of renal function (creatinine > 2.5 UNL) or hepatic (bilirubin or ALT / AST > 3 UNL), unless it is suspected to be due to the disease. 4. HIV positive patients 5. Patient previously treated for the DLBCL 6. Positive determination of chronic hepatitis B (defined as positive serology for HBsAg). It will be allowed to enroll patients with hidden or previous hepatitis (defined as positive antibodies against the core of the hepatitis B virus [HBcAb] and HBsAg negative) if undetectable HBV DNA. 7. Positive results for hepatitis C (antibody serology for hepatitis C virus [HCV]). Patients with HCV positive may participate only if the result of the PCR is negative for HCV RNA. 8. Patients with previous history of cardiac disease: ventricular ejection fraction < 50%. 9.

Primary: Primary

| | |
|-----------------|---------|
| End point title | Primary |
|-----------------|---------|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Proportion of patients with event -free survival at 2 years.

| End point values | EXPERIMENTAL ARM BR- CAP21X2 | CONTROL ARM R-CHOP21X2 | | |
|-----------------------------|------------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 60 | 61 | | |
| Units: . | 60 | 61 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Complete analysis |
| Comparison groups | EXPERIMENTAL ARM BR-CAP21X2 v CONTROL ARM R-CHOP21X2 |
| Number of subjects included in analysis | 121 |
| Analysis specification | Post-hoc |
| Analysis type | non-inferiority |
| P-value | < 0.25 ^[1] |
| Method | t-test, 1-sided |

Notes:

[1] - If the p-value

associated with the test was below 0.25, we considered the test to be positive, and we declared the combination to be effective.

Secondary: Secondary

| | |
|-----------------|-----------|
| End point title | Secondary |
|-----------------|-----------|

End point description:

1. Event -free survival at 2 years in different biological DLBCL subgroups: CGB vs non-CGB. 2. Overall survival at 2 years in patients diagnosed of DLBCL with aIPI > 1 or aIPI=1 with elevated levels of beta 2-microglobulin (above UNL). 3. Overall response rate and complete remissions in patients diagnosed of DLBCL with aIPI > 1 or aIPI=1 with elevated levels of beta 2-microglobulin (above UNL). 4. Toxicity according to the CTC criteria (version 3.0) of the National Cancer Institute (NCI). <http://ctep.cancer.gov/reporting/ctcnew.html> 5. To evaluate the predictive value for EFS of interim PET/CT evaluation after 2 and 4 cycles of chemotherapy. 6. To identify clinical and biological prognostic factors for response and survival

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

1. Event -free survival at 2 years in different biological DLBCL subgroups: CGB vs non-CGB. 2. Overall survival at 2 years in patients diagnosed of DLBCL with aIPI > 1 or aIPI=1 with elevated levels of beta 2-microglobulin (above

| End point values | EXPERIMENTAL ARM BR- CAP21X2 | CONTROL ARM R-CHOP21X2 | | |
|-----------------------------|------------------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 60 | 61 | | |
| Units: . | 60 | 60 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

A total of 121 patients received at least 1 infusion of study treatment and were included in the safety analysis. The analysis was performed considering the worst grade of reported AE per patient and considering a sample size of 121 patients.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|-----------|
| Dictionary name | NCI-CTCAE |
|-----------------|-----------|

| | |
|--------------------|-----|
| Dictionary version | 3.0 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|-----------------------------|
| Reporting group title | EXPERIMENTAL ARM BR-CAP21X2 |
|-----------------------|-----------------------------|

Reporting group description:

Six cycles of treatment with bortezomib were administered subcutaneously at a dose of 1.3 mg/m² on days 1, 8, and 15, followed by rituximab iv at a dose of 375 mg/m² on day 1 followed by chemotherapy: cyclophosphamide 750 mg/m² iv on day 1 + Adriamycin 50 mg/m² iv on day 1 + prednisone 100 mg oral on days 1-5. The cycles were administered every 21 days

| | |
|-----------------------|------------------------|
| Reporting group title | CONTROL ARM R-CHOP21X2 |
|-----------------------|------------------------|

Reporting group description:

Six cycles of treatment with R-CHOP were administered: Rituximab 375 mg/m² iv on day 1 followed by CHOP-type chemotherapy (cyclophosphamide 750 mg/m² iv on day 1 + Adriamycin 50 mg/m² iv on day 1 + vincristine 1.4 mg/m² iv (maximum 2 mg) on day 1 + prednisone 100 mg oral on days 1-5). The cycles were administered every 21 days.

The administration of rituximab was performed as an iv infusion. The first infusion was started at a rate of 50 mg/hour, and after the first 30 minutes, the dose could be increased in increments of 50 mg/hour every 30 minutes up to a maximum of 400 mg/hour. Subsequent infusions could be administered at an initial rate of 100 mg/hour and increased by 100 mg/hour at intervals of 30 minutes to a maximum of 400 mg/hour.

| Serious adverse events | EXPERIMENTAL ARM BR-CAP21X2 | CONTROL ARM R- CHOP21X2 | |
|---|--------------------------------|----------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 60 (10.00%) | 3 / 61 (4.92%) | |
| number of deaths (all causes) | 33 | 33 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Infections and infestations | | | |
| Infection | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | 2 / 61 (3.28%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Anaemia | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 3 / 60 (5.00%) | 1 / 61 (1.64%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | 0 / 61 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | EXPERIMENTAL ARM BR-CAP21X2 | CONTROL ARM R- CHOP21X2 | |
|---|--------------------------------|----------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 13 / 60 (21.67%) | 7 / 61 (11.48%) | |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 10 / 60 (16.67%) | 5 / 61 (8.20%) | |
| occurrences (all) | 1 | 1 | |
| Platelet count abnormal | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | 2 / 61 (3.28%) | |
| occurrences (all) | 1 | 1 | |

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

None reported