



Clinical trial results:

Significance of prognostic and predictive factors for the efficacy and safety of neoadjuvant chemotherapy in combination with chemoradiation administered in patients with locally advanced cervical cancer.

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2008-006309-17 |
| Trial protocol | LT |
| Global end of trial date | 01 October 2013 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 15 January 2022 |
| First version publication date | 15 January 2022 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | A7-14. |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Institute of Oncology of Vilnius University |
| Sponsor organisation address | Santariskiu 1, Vilnius, Lithuania, |
| Public contact | Lina Daukantiene, Institute of Oncology of Vilnius University, 00370 52786709, lina.daukantiene@nvi.lt |
| Scientific contact | Lina Daukantiene, Institute of Oncology of Vilnius University, 00370 52786709, lina.daukantiene@nvi.lt |

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 | 01 November 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 01 October 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 01 October 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

1. To evaluate the efficacy of treatment with neoadjuvant cisplatin+gemcitabine based chemotherapy and with concurrent cisplatin+gemcitabine+radiotherapy in locally advanced cervical cancer (defined as response to treatment and progression free survival);
2. To evaluate treatment safety.

Protection of trial subjects:

Treated in routine care.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 12 April 2010 |
| 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 | Lithuania: 36 |
| Worldwide total number of subjects | 36 |
| EEA total number of subjects | 36 |

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) | 35 |
| From 65 to 84 years | 1 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Women with locally advanced stage IIB-IIIB cervical cancer.

Pre-assignment

Screening details:

36 subjects previously received no treatment for cervical cancer

Period 1

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

Blinding implementation details:

NA

Arms

| | |
|------------------|---------------|
| Arm title | Overall trial |
|------------------|---------------|

Arm description:

NA

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Gemcitabin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for infusion |
| Routes of administration | Concentrate for solution for infusion |

Dosage and administration details:

125 mg/m² gemcitabin was given on once a week basis for 4 weeks as a neoadjuvant chemotherapy.

125mg /m² gemcitabin was given on once a week basis during external beam radiotherapy for 5 weeks

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Cisplatin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Infusion |

Dosage and administration details:

30 mg/m² cisplatin was given on once a week basis for 4 weeks as a neoadjuvant chemotherapy. 40mg

/m² cisplatin was given on once a week basis during external beam radiotherapy for 5 weeks

| | |
|---------------------------------------|---------------|
| Number of subjects in period 1 | Overall trial |
| Started | 36 |
| Completed | 36 |

Baseline characteristics

Reporting groups

| | |
|------------------------------|---------------|
| Reporting group title | Overall trial |
| Reporting group description: | |
| Overall trial | |

| Reporting group values | Overall trial | Total | |
|------------------------|---------------|-------|--|
| Number of subjects | 36 | 36 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 35 | 35 | |
| From 65-84 years | 1 | 1 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 36 | 36 | |

Subject analysis sets

| | |
|---|--------------------------|
| Subject analysis set title | Neoadjuvant chemotherapy |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| All enrolled patients who received neoadjuvant chemotherapy | |
| Subject analysis set title | Overall trial |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | |
| All enrolled patients who received neoadjuvant chemotherapy followed by chemoradiation. | |

| Reporting group values | Neoadjuvant chemotherapy | Overall trial | |
|------------------------|--------------------------|---------------|--|
| Number of subjects | 36 | 36 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | | | |
| From 65-84 years | | | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 36 | 36 | |

End points

End points reporting groups

| | |
|--|--------------------------|
| Reporting group title | Overall trial |
| Reporting group description: NA | |
| Subject analysis set title | Neoadjuvant chemotherapy |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: All enrolled patients who received neoadjuvant chemotherapy | |
| Subject analysis set title | Overall trial |
| Subject analysis set type | Per protocol |
| Subject analysis set description: All enrolled patients who received neoadjuvant chemotherapy followed by chemoradiation. | |

Primary: Overall response rate

| | |
|---|-----------------------|
| End point title | Overall response rate |
| End point description: | |
| End point type | Primary |
| End point timeframe: 12 APR 2010 - 01 OCT 2013 | |

| End point values | Overall trial | Neoadjuvant chemotherapy | Overall trial | |
|-----------------------------|-----------------|--------------------------|----------------------|--|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 36 | 36 | 36 | |
| Units: Percent | 36 | 36 | 36 | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Descriptive statistics |
| Statistical analysis description: Frequencies and percentages were used for the categorical measures. | |
| Comparison groups | Overall trial v Overall trial v Neoadjuvant chemotherapy |
| Number of subjects included in analysis | 108 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[1] |
| P-value | < 0.05 ^[2] |
| Method | descriptive statistics |

Notes:

[1] - Frequencies and percentages were used for the categorical measures.

[2] - Statistical hypothesis test was not performed

Adverse events

Adverse events information

Timeframe for reporting adverse events:

12 APR 2010 - 01 OCT 2013

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

Dictionary used

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

| | |
|--------------------|---|
| Dictionary version | 3 |
|--------------------|---|

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | Overall trial |
|-----------------------|---------------|

Reporting group description: -

| Serious adverse events | Overall trial | | |
|---|-----------------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 36 (2.78%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | Additional description: Grade III | | |
| subjects affected / exposed | 1 / 36 (2.78%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Overall trial | | |
|---|-------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 36 / 36 (100.00%) | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 36 / 36 (100.00%) | | |
| occurrences (all) | 4 | | |
| Neutropenia | | | |
| subjects affected / exposed | 36 / 36 (100.00%) | | |
| occurrences (all) | 17 | | |
| Thrombocytopenia | | | |

| | | | |
|-----------------------------|-------------------|--|--|
| subjects affected / exposed | 36 / 36 (100.00%) | | |
| occurrences (all) | 7 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 36 / 36 (100.00%) | | |
| occurrences (all) | 3 | | |

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