



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.
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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
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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
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Dictionary used

Dictionary name	NCI CTCAE
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Dictionary version	3
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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	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