



Clinical trial results:

A Randomised phase II study with the combination of Xeloda (Capecitabine) plus Navelbine Oral (Vinorelbine) day 1 and day 8 every 3. week versus Xeloda plus Navelbine Oral given metronimic as 1. or 2. line chemotherapy to patients with HER2 negative local metastatic breastcancer.

Summary

EudraCT number	2011-003564-72
Trial protocol	DK
Global end of trial date	11 December 2019

Results information

Result version number	v1 (current)
This version publication date	21 August 2021
First version publication date	21 August 2021
Summary attachment (see zip file)	Article published in Acta Oncologica (Metronomic treatment of vinorelbine with oral capecitabine is tolerable in the randomized Phase 2 study XeNa including patients with HER2 non.pdf)

Trial information

Trial identification

Sponsor protocol code	Aarhus University Hospital
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01941771
WHO universal trial number (UTN)	-
Other trial identifiers	Aarhus University Hospital: Department of oncology

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul Jensens Boulevard 99, Aarhus, Denmark, 8200
Public contact	Clinical Trial Unit , Aarhus University Hospital, 0045 89494440, svelan@rm.dk
Scientific contact	Clinical Trial Unit , Aarhus University Hospital, 0045 89494440, svelan@rm.dk
Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul Jensens Boulevard 99, Aarhus, Denmark,
Public contact	clinical research unit, Department of oncology, 45 24839896, annbrem@rm.dk
Scientific contact	clinical research unit, Department of oncology, 45 24839896, annbrem@rm.dk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric	No
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investigation plan (PIP)	
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 October 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	
Global end of trial date	11 December 2019
Was the trial ended prematurely?	No
Notes:	

General information about the trial

Main objective of the trial:	
To compare the effect of an experimental chemotherapy arm, where Navelbine is given together with Xeloda in a metronomic manner to a standard treatment arm of Navelbine and Xeloda. We expected that the experimental arm was better than the standard treatment arm	
Protection of trial subjects:	
Data was anonymized. No other protection of trial subjects	
Background therapy:	
Standart supportive care for nausea and diahrrea if nessesary.	
Standard treatment of pain and infections if any	
Evidence for comparator: -	
Actual start date of recruitment	02 January 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	Denmark: 120
Worldwide total number of subjects	120
EEA total number of subjects	120
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)	100
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at the Department of Oncology, University Hospital of Aarhus

Pre-assignment

Screening details:

Patients treated for metastatic breast cancer in our department.

Pre-assignment period milestones

Number of subjects started	120
Number of subjects completed	120

Period 1

Period 1 title	inclusion in the trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

open randomised trial

Arms

Are arms mutually exclusive?	Yes
Arm title	arm a

Arm description:

standard chemotreaty with xeloda day 1-14 and navalbine day 1-8

Arm type	Active comparator
Investigational medicinal product name	Navelbine
Investigational medicinal product code	L01CA
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use

Dosage and administration details:

please see the article

Investigational medicinal product name	Navelbine
Investigational medicinal product code	L01CA
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use

Dosage and administration details:

please see the article

Arm title	arm b
Arm description:	metronomic vinorelbine and standard xeloda day 1-14
Arm type	Experimental

Investigational medicinal product name	Navelbine
Investigational medicinal product code	L01CA
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use

Dosage and administration details:

please see the article

Number of subjects in period 1	arm a	arm b
Started	62	58
Completed	60	58
Not completed	2	0
Consent withdrawn by subject	1	-
Protocol deviation	1	-

Baseline characteristics

Reporting groups

Reporting group title	inclusion in the trial
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Reporting group description: -

Reporting group values	inclusion in the trial	Total	
Number of subjects	120	120	
Age categorical			
age			
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	20	20	
85 years and over	0	0	
Gender categorical			
sex			
Units: Subjects			
Female	120	120	
Male	0	0	

Subject analysis sets

Subject analysis set title	arm a and arm b
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Randomized trial Arm conventional chemotrerpny, trial arm B metronomic chemotherapy

Reporting group values	arm a and arm b		
Number of subjects	118		
Age categorical			
age			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	98		
From 65-84 years	20		

85 years and over	0		
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Gender categorical			
sex			
Units: Subjects			
Female	118		
Male	0		

End points

End points reporting groups

Reporting group title	arm a
Reporting group description:	
standard chemotreaty with xeloda day 1-14 and navalbine day 1-8	
Reporting group title	arm b
Reporting group description:	
metronomic vinorelbine and standard xeloda day 1-14	
Subject analysis set title	arm a and arm b
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Randomized trial Arm conventional chemotrery, trial arm B metronomic chemotherapy	

Primary: response rate

End point title	response rate
End point description:	
Recist 1.0	
End point type	Primary
End point timeframe:	
2012-2019	

End point values	arm a	arm b		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	58		
Units: patients benefits of treatments	60	58		

Statistical analyses

Statistical analysis title	calculation of response rates
Comparison groups	arm a v arm b
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≥ 0.05
Method	Logrank
Parameter estimate	Odds ratio (OR)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard deviation

Adverse events

Adverse events information

Timeframe for reporting adverse events:

2012-2019

Adverse event reporting additional description:

See attached article

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4
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Reporting groups

Reporting group title	adverse events
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Reporting group description:

Please see the table in the article for details

Serious adverse events	adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 118 (27.97%)		
number of deaths (all causes)	80		
number of deaths resulting from adverse events	2		
General disorders and administration site conditions			
stated in the article	Additional description: Please see the article		
subjects affected / exposed	33 / 118 (27.97%)		
occurrences causally related to treatment / all	33 / 33		
deaths causally related to treatment / all	2 / 2		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	80 / 118 (67.80%)		
Blood and lymphatic system disorders			
Stated in the article	Additional description: Stated in the article		
subjects affected / exposed	80 / 118 (67.80%)		
occurrences (all)	80		

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.

Phase 2 study. Not powered to compare survival the two arms.
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Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/33259244>