



Clinical trial results:

Can Eribulin enhance the effect of subsequent endocrine therapy?- a phase 2 study for patients with ER positive HER2 normal metastatic breast cancer

Summary

EudraCT number	2020-004909-32
Trial protocol	DK
Global end of trial date	26 October 2024

Results information

Result version number	v1 (current)
This version publication date	04 December 2024
First version publication date	04 December 2024

Trial information

Trial identification

Sponsor protocol code	5798002749939
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Department of Oncology University Hospital of Aarhus
Sponsor organisation address	Palle Juul Jensens Boulevard 99, Aarhus N, Denmark, 8200
Public contact	Department of Oncology, Anne Sofie Brems-Eskildsen, 45 24839896, anbrem@onerm.dk
Scientific contact	Department of Oncology, Anne Sofie Brems-Eskildsen, 45 24839896, annebrem@rm.dk

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	26 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 October 2024
Global end of trial reached?	Yes
Global end of trial date	26 October 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Can we, by 4 series of chemotherapy treatment with Eribulin, enhance the effect of 3. line antiestrogenen treatment with exemestane, as compared to 2 linie anti-estrogene treatment with fulvestrant monotherapy (before entering the study).

Protection of trial subjects:

good clinical practice

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2021
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	Denmark: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	4
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

8 patients were recruited in department of oncology, Aarhus

Pre-assignment

Screening details:

Patients were included from the Department of Oncology at the University Hospital of Aarhus from 2022 to 2024

Period 1

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

Arms

Arm title	singel arm study
Arm description: -	
Arm type	singel arm
Investigational medicinal product name	eribulin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

dosed after surface

Number of subjects in period 1	singel arm study
Started	8
Completed	8

Baseline characteristics

Reporting groups

Reporting group title	study period
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Reporting group description: -

Reporting group values	study period	Total	
Number of subjects	8	8	
Age categorical			
adults			
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
median	64		
full range (min-max)	53 to 80	-	
Gender categorical			
Units: Subjects			
Female	8	8	
Male	0	0	

End points

End points reporting groups

Reporting group title	singel arm study
Reporting group description: -	

Primary: Response of exemestane

End point title	Response of exemestane ^[1]
End point description: descriptive analysis	
End point type	Primary
End point timeframe: during the study period	

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: we have only one group in the study. The statistcal plan was to make af desctiptive analysis

End point values	singel arm study			
Subject group type	Reporting group			
Number of subjects analysed	8 ^[2]			
Units: 8	8			

Notes:

[2] - only 8 patientes included in the study

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

no new adverse events were detected in the trial. Both drugs in the study were well known.

Adverse event reporting additional description:

as no new adverse events were detected the threshold for reporting the AE was not reached.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	SNOMED CT
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Dictionary version	4
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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: we have no new signal in the study. We saw febrile neutropenia in 3 out of 8 patients as expected with the treatment with Eribulin.

More over one patient had liver failure due to breast cancer progression during the treatment.

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? Yes

Date	Interruption	Restart date
01 October 2024	The trial stopped due to lack of effect in the study population and we only treated 8 out of the planned 42 patientes due to lack of effect	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The trial were stoped after including 8 out of planed 42 patients due to no responders were seen. And it therefore were considered unlikely that we would get resopnders and effect of the studied startegy.
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Notes: