



Clinical trial results:

A Safety and feasibility study of standard dosing day 1 carboplatin AUC 5 every 3rd weeks with daily Navelbine® 20/30mg (oral) during 4 cycles (12 weeks) for the treatment of advanced NSCLC; A feasibility study

Summary

EudraCT number	2017-000659-23
Trial protocol	DK
Global end of trial date	08 October 2020

Results information

Result version number	v1 (current)
This version publication date	08 March 2022
First version publication date	08 March 2022
Summary attachment (see zip file)	Metronomic oral vinorelbine doublet chemotherapy with carboplatin in treatment of advanced lung cancer: a feasibility and safety study (Summery til EurDra.docx)

Trial information

Trial identification

Sponsor protocol code	220365-2017
-----------------------	-------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AUH, kræftafdeling
Sponsor organisation address	Valdemars Have 28, 3. tv., Aarhus C, Denmark, 8000
Public contact	Clinical Research Unit (KFE), Aarhus University Hospital (AUH), mariakandi@gmail.com
Scientific contact	Clinical Research Unit (KFE), Aarhus University Hospital (AUH), +45 29906907, mariakandi@gmail.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 October 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 February 2019
Global end of trial reached?	Yes
Global end of trial date	08 October 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary objectives:

Evaluating the side effects (toxicity and feasibility, adverse events grade 2-5 (CTC)) during the first 84 days (12 weeks) of treatment.

Protection of trial subjects:

Trial subjects reported any toxicity, that occurred between cycles or in between visits. Moreover, during the entire treatment period trial subjects kept a diary. The subjects were asked to register any adverse event in their diary. Five visits were scheduled during the treatment period.

Background therapy:

Carboplatinum was given as backbone treatment to all trial subjects accordingly to national guidelines.

Evidence for comparator: -

Actual start date of recruitment	01 May 2018
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	8

From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

01/may/2018 -28/feb/2019.

Dept. of Oncology, Aarhus University Hospital, Denmark.

Pre-assignment

Screening details:

Subjects with incurable NSCLC, candidates for 1st-line chemotherapy (PD-L1<50%), were included.

Period 1

Period 1 title	From May 2018 to February 2019 (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	active comparator
------------------	-------------------

Arm description:

the study is open label non randomized study

Arm type	open label non randomized arm
Investigational medicinal product name	vinorelbine
Investigational medicinal product code	L01CA04
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

20/30 mg daily in maximum 12 weeks in combination with carboplatinum (given every 3 weeks max 4 series)

Number of subjects in period 1	active comparator
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	From May 2018 to February 2019
-----------------------	--------------------------------

Reporting group description: -

Reporting group values	From May 2018 to February 2019	Total	
Number of subjects	20	20	
Age categorical			
Age median 70.5 (49-82)			
Units: Subjects			
18-85 years	20	20	
Gender categorical			
Units: Subjects			
Female	16	16	
Male	4	4	

End points

End points reporting groups

Reporting group title	active comparator
Reporting group description: the study is open label non randomized study	

Primary: toxicity

End point title	toxicity ^[1]
End point description:	

End point type	Primary
End point timeframe: May 2018 - June 2019	

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: this is a pilot and safety study with only 20 patients whose toxicity and data were descriptive.

End point values	active comparator			
Subject group type	Reporting group			
Number of subjects analysed	18 ^[2]			
Units: 220				
number (not applicable)				
toxicity	113			

Notes:

[2] - 18 patient was included in toxicity data

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

All adverse events on subjects were registered from baseline and until end of treatment period for last trial subject.

Adverse event reporting additional description:

Trial subjects were instructed to report any toxicity, that occurred between cycles or in between visits, using an electronic adverse event report system (AmbuFlex(R)). Moreover, during the entire treatment period subjects kept a diary.

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

Dictionary used

Dictionary name	CTCAE
-----------------	-------

Dictionary version	4.03
--------------------	------

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: see reported table over adverse events section in attached PDF file

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