Clinical trial results:
Phase II trial of capecitabine (Xeloda®) + nab-paclitaxel (Abraxane®) in patients with metastatic pancreatic cancer

Summary

EudraCT number	2013-001714-15
Trial protocol	AT
Global end of trial date	22 July 2017

Results information

Result version number	v1 (current)
This version publication date	19 February 2021
First version publication date	19 February 2021

Trial information

Trial identification

Sponsor protocol code	Met.Panc.01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	MedUniWien
Sponsor organisation address	Spitalgasse 23, Wien, Austria, 1090
Public contact	Marika Rosner, MedUniWien, +43 14040044450, marika.rosner@meduniwien.ac.at
Scientific contact	Markus Raderer, MedUniWien, +43 14040044450, markus.raderer@meduniwien.ac.at

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	31 January 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 January 2015
Global end of trial reached?	Yes
Global end of trial date	22 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Objective response rate of Capecitabine + Nab-Paclitaxel as first-line chemotherapy in patients with metastatic pancreatic cancer

Protection of trial subjects:

CT Thorax/Abdomen every 8 weeks

Background therapy:

antiemetics before and 3 days after administration of nab-paclitaxel

Evidence for comparator: -

Actual start date of recruitment	05 August 2013
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	Austria: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	16
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between December 2013 and January 2015, 30 patients were enrolled into this single-Center at the University Hospital Vienna.

Pre-assignment

Screening details:

30 patients were screened according to the inclusion and exclusion criteria

Period 1

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

Arms

Arm title	treatment arm

Arm description:

There is only one arm

Arm type	Experimental
Investigational medicinal product name	Nab-Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

125 mg/m2 intravenously on days 1 and 8) every 3 weeks

Investigational medicinal product name	capacitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Capecitabine 825 mg/m2, day 1 to 15,every 3 weeks.

Number of subjects in period 1	treatment arm
Started	30
Completed	29
Not completed	1
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	30	30	
Age categorical 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)	16	16	
From 65-84 years	14	14	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	14	14	
Male	16	16	

Subject analysis sets

Subject analysis set title	Overall trial
Subject analysis set type	Full analysis

Subject analysis set description:

Objective response rate of Capecitabine + Nab-Paclitaxel as first-line chemotherapy in patients with metastatic pancreatic cancer

Reporting group values	Overall trial		
Number of subjects	30		
Age categorical 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)	16		
From 65-84 years	14		
85 years and over	0		

Gender categorical Units: Subjects			
Female	14		
Male	16		

End points

End points reporting groups

Reporting group title	treatment arm
Reporting group description:	
There is only one arm	
Subject analysis set title	Overall trial
Subject analysis set type	Full analysis
Subject analysis set description:	
Objective response rate of Capecitabine + Nab-Paclitaxel as first-line chemotherapy in patients with metastatic pancreatic cancer	

Primary: Objective tumor response

End point title	Objective tumor response
End point description:	
Objective tumor response according to RECIST criteria	
End point type	Primary
End point timeframe:	
From baseline until end of treatment	

End point values	treatment arm	Overall trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	30	30		
Units: number	30	30		

Statistical analyses

Statistical analysis title	Objective response rate
Comparison groups	treatment arm v Overall trial
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.05
Method	Simon’s two-stage design

Notes:

[1] - descriptive statistics

Adverse events

Adverse events information

Timeframe for reporting adverse events:

after the patient has signed the informed consent form until post treatment visit

Assessment type	Systematic

Dictionary used

Dictionary name	NCI CTCAE
Dictionary version	4.0

Reporting groups

Reporting group title	Treatment-related AEs

Reporting group description: -

Serious adverse events	Treatment-related AEs		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 30 (16.67%)		
number of deaths (all causes)	17		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
neutopenia			
subjects affected / exposed	5 / 30 (16.67%)		
occurrences causally related to treatment / all	5 / 5		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Treatment-related AEs		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 30 (100.00%)		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	17 / 30 (56.67%)		
occurrences (all)	23		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	18 / 30 (60.00%)		
occurrences (all)	18		
Anaemia			

subjects affected / exposed occurrences (all)	5 / 30 (16.67%) 5		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	 10 / 30 (33.33%) 10		

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.

no limitations

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27034791