Clinical trial results:
Nab-Paclitaxel (Abraxane®) and Gemcitabine as first line therapy in patients with cholangiocarcinoma ineligible for cisplatin-based chemotherapy – a pilot study
The NACHO trial (GEMNABCCC-001)

Summary

EudraCT number	2014-004981-52
Trial protocol	DE
Global end of trial date	10 October 2019

Results information

Result version number	v1 (current)
This version publication date	15 August 2022
First version publication date	15 August 2022
Summary attachment (see zip file)	CSR_2014-004981-52 (NACHO_CSR_2022-07-29.pdf)

Trial information

Trial identification

Sponsor protocol code	GEMNABCCC-001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	AX-CL-OTHER-PI-003916 : Celgene number

Notes:

Sponsors

Sponsor organisation name	University Hospital Essen
Sponsor organisation address	Hufelandstr. 55, Essen, Germany, 45147
Public contact	PI, University Hospital Essen, +49 02017231791, gabriele.linden@uk-essen.de
Scientific contact	PI, University Hospital Essen, +49 02017231791, gabriele.linden@uk-essen.de

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 July 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 October 2019
Global end of trial reached?	Yes
Global end of trial date	10 October 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary objective:
To determine the efficacy of Gemcitabine/nab-Paclitaxel in first-line therapy of patients with cholangiocarcinoma ineligible for Cisplatin-based therapy. Results of the first 10 evaluable patients will be compared to patient outcomes from the cancer registry of the West German Cancer Center (patients treated with Gemcitabine-combinations, patients treated with monotherapies). Primary endpoint will be overall response rate (ORR) (complete remission and partial remission)

Protection of trial subjects:

AE were measured at every visit.
The regulatory basis of the conduct of this study consisted of the Declaration of Helsinki (in its current version), the AMG [German Medicinal Products Act], in particular Sections 40-42 in the current versions, the guidelines of Good Clinical Practice (ICH-GCP: International Conference on Harmonisation –Good Clinical Practice) valid since 17-Jan-1997, and the GCP-regulation of 09-Aug-2004 (last change of 15-Mar-2006).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 January 2016
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	Germany: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	7
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment 06.Dec2016 - 05.Jul 2017

Pre-assignment

Screening details:

all screened patients were registered. in total, 10 patients started therapy. There was no screen failure

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	Nab-Paclitaxel and Gemcitabine

Arm description:

Nab-Paclitaxel (Abraxane®) and Gemcitabine

Arm type	Experimental
Investigational medicinal product name	nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nab-Paclitaxel (Abraxane®)
125mg/m² i.v. day 1, 8, 15

for patients with bilirubin 1.5-3ULN
Nab-Paclitaxel (Abraxane®)
100mg/m² i.v. day 1, 8, 15

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Gemcitabine
1000mg/m² i.v. day 1, 8, 15

repeat the cycle at day 28, until disease progression

For Patients with elevated bilirubin values >1.5-3x ULN):
Gemcitabine
800mg/m² i.v. day 1, 8, 15

Number of subjects in period 1	Nab-Paclitaxel and Gemcitabine
Started	10
Completed	10

Baseline characteristics

End points

End points reporting groups

Reporting group title	Nab-Paclitaxel and Gemcitabine
Reporting group description: Nab-Paclitaxel (Abraxane®) and Gemcitabine	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description: Intention-To-treat population	

Primary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)[1]
End point description: Altogether 10 patients were enrolled into the trial and received at least one cycle of chemotherapy (ITT-population), In total 4 of the ITT set had CR or PR as best response; this amounted to an ORR of 40%. DCR (CR+PR+SD) was 80%.	
End point type	Primary
End point timeframe: Registration to EOS	

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: see full data set

End point values	ITT			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: 4				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Screening to EOS	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	3.0

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

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 full data set

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