Clinical trial results:
DANSAC-open: A multicenter, open label study to investigate the efficacy and tolerability of olanzapine in patients with advanced cancer not receiving chemotherapy or irradiation.

Summary

EudraCT number	2015-002294-38
Trial protocol	DK
Global end of trial date	05 September 2018

Results information

Result version number	v1 (current)
This version publication date	01 January 2020
First version publication date	01 January 2020
Summary attachment (see zip file)	DANSAC_open, article (OPEN_artikel.pdf)

Trial information

Trial identification

Sponsor protocol code	DANSAC-open

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	JB Winsløws Vej 4, Odense, Denmark, 5000
Public contact	Signe Harder, Odense University Hospital, +45 4525382590, signe.harder@rsyd.dk
Scientific contact	Signe Harder, Odense University Hospital, +45 4525382590, signe.harder@rsyd.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	05 September 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 September 2018
Global end of trial reached?	Yes
Global end of trial date	05 September 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Objectives: The primary objective is to test if olanzapine 10 mg is effective in patients with advanced cancer not receiving chemotherapy or irradiation.
Hypotheses: Administration of olanzapine will result in a change in nausea score from baseline to 24 hours later exceeding 30%. In patients included because of vomiting only (nausea score less than moderate), the primary parameter will be change in number of emetic episodes from baseline to 24 hours later.

Protection of trial subjects:

Close follow-up, minimal procedures involved for the patient

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2016
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	15
From 65 to 84 years	24

85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Slow recruitment

Pre-assignment

Screening details:

Patients both screened and directly referred for the trial (29 screened, 11 referred)

Period 1

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

Arms

Arm title	All patients

Arm description: -

Arm type	Experimental
Investigational medicinal product name	olanzapine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection, Orodispersible tablet
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

First dose intravenous, following four doses as an orodispersable tablet

Number of subjects in period 1	All patients
Started	40
Completed	34
Not completed	6
Consent withdrawn by subject	1
Adverse event, non-fatal	1
Failing inclusion criteria during the study	4

Baseline characteristics

Reporting groups	
Reporting group title	Overall

Reporting group description: -

Reporting group values	Overall	Total	
Number of subjects	40	40	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
median	67		
full range (min-max)	37 to 88	-	
Gender categorical Units: Subjects			
Female	22	22	
Male	18	18	

End points

End points reporting groups

Reporting group title	All patients

Reporting group description: -

Primary: Effect

End point title	Effect[1]

End point description:

Number of patients reporting a lower degree of nausea or a lower number of emetic episodes at 24 hous compared to baseline

End point type	Primary

End point timeframe:

From baseline to 24 hours

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: Reporting a single arm study, and even though the information button say I can choose just one arm, the validation of data keep making warnings despite many efforts to correct the error.

End point values	All patients			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: Number of patients	36			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Adverse events evaluated 24 hours after first dose and at seven days	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.0

Reporting groups	
Reporting group title	All patients

Reporting group description: -

Serious adverse events	All patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	All patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 40 (37.50%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 40 (20.00%)		
occurrences (all)	8		
Dizziness			
subjects affected / exposed	8 / 40 (20.00%)		
occurrences (all)	8		
Sedation			
subjects affected / exposed	7 / 40 (17.50%)		
occurrences (all)	7		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 November 2016	1: change in time of medication from morning to bedtime 2: Removal of bloodsamples
01 September 2017	1: Change in exclusion criteria not allowing antineoplastic treatment from 4 weeks to 2 weeks 2: Expanding inclusion time to 36 months 3: Allowing dose reductions in case of adverse events

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported