



Clinical trial results:

DANSAC-RCT: Fosaprepitant in patients with advanced cancer not receiving chemotherapy or irradiation; A multicenter, randomized, double-blind, placebo-controlled study.

Summary

EudraCT number	2015-003070-33
Trial protocol	DK
Global end of trial date	31 July 2017

Results information

Result version number	v1 (current)
This version publication date	29 October 2017
First version publication date	29 October 2017

Trial information

Trial identification

Sponsor protocol code	DANSAC-RCT
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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	Sdr Boulevard 29, Odense C, Denmark, 5000
Public contact	Signe Harder, Odense University Hospital, 45 25382590, signe.harder@rsyd.dk
Scientific contact	Signe Harder, Odense University Hospital, 45 25382590, 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	02 October 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 July 2017
Global end of trial reached?	Yes
Global end of trial date	31 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to compare whether the administration of the neurokinin1-receptor antagonist (NK1-RA) fosaprepitant dimeglumine results in a significant improvement in nausea scores from baseline to 24 hours as compared with placebo. 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.

Protection of trial subjects:

Patients were followed up at 24 hours and 7 days and were given contact information to study personnel available around the clock.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 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: 3
Worldwide total number of subjects	3
EEA total number of subjects	3

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)	2
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients recruited from hospitals, 3 study sites opened, all 3 recruited patients included by 1 study site.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	3
Number of subjects completed	3

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

All personell blinded except two study nurses in charge of mixing the active/placebo drug and one monitor checking for correct assignment during first controlvisit.

Subjects were unblinded after all records had been electronic entered and locked

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description:

Fosaprepitant 150 ml infused over 30 min

Arm type	Experimental
Investigational medicinal product name	fosaprepitant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

150 mg given as a 30 min infusion

Arm title	Placebo
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Arm description:

Saline

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Matching saline

Number of subjects in period 1	Active	Placebo
Started	1	2
Completed	1	2

Baseline characteristics

Reporting groups

Reporting group title	Overall
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Reporting group description: -

Reporting group values	Overall	Total	
Number of subjects	3	3	
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)	2	2	
From 65-84 years	1	1	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	60		
full range (min-max)	43 to 72	-	
Gender categorical			
Units: Subjects			
Female	1	1	
Male	2	2	

End points

End points reporting groups

Reporting group title	Active
Reporting group description: Fosaprepitant 150 ml infused over 30 min	
Reporting group title	Placebo
Reporting group description: Saline	

Primary: Nausea at 24 hours compared to baseline

End point title	Nausea at 24 hours compared to baseline ^[1]
End point description:	
End point type	Primary
End point timeframe: 0-24 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: Very low number of patientes included, no analyses performed

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	2		
Units: 0-4				
number (not applicable)	0	0.5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

7 days

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	Active
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Reporting group description: -

Serious adverse events	Placebo	Active	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Placebo	Active	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	

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: Very low number of patients included, no adverse events recorded

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.

Very early termination due to a very low number of patients included, no analyses done on the data.

Notes: