



Clinical trial results:

PreMENAC: Multimodal Exercise/Nutrition/Anti-inflammatory treatment for Cachexia: A feasibility study (phase II)

Summary

EudraCT number	2010-022897-14
Trial protocol	NO GB DK
Global end of trial date	01 September 2014

Results information

Result version number	v1 (current)
This version publication date	18 September 2016
First version publication date	18 September 2016
Summary attachment (see zip file)	Results remenac summary (2016-09-01 EudraCT_preMENAC resultat.docx)

Trial information

Trial identification

Sponsor protocol code	PreMENAC-2011-01
-----------------------	------------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01419145
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	NNorwegian University of Science and Technology (NTNU)
Sponsor organisation address	PB, Trondheim, Norway, 7491
Public contact	European Palliative Care Research Centre (PRC), European Palliative Care Research Centre (PRC), Department of Cancer Research and Molecular Me, prc@ntnu.no
Scientific contact	European Palliative Care Research Centre (PRC), European Palliative Care Research Centre (PRC), Department of Cancer Research and Molecular Me, prc@ntnu.no

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 September 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The overall objectives are the feasibility of patient recruitment, compliance to the multimodal intervention as well as the assessment of possible contamination of the control group. This will be assessed by:

- Patient recruitment
- Compliance to the intervention and attrition
- Compliance with the data collection procedures
- Contamination of the control group

Protection of trial subjects:

There were no safety concerns identified. Eventual SAE and AEs were evaluated in the trial using CTCAE 3.0.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 October 2011
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	Norway: 23
Country: Number of subjects enrolled	United Kingdom: 23
Worldwide total number of subjects	46
EEA total number of subjects	46

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)	30
From 65 to 84 years	16
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screened for eligibility (n=399)

Pre-assignment period milestones

Number of subjects started	46
Number of subjects completed	46

Period 1

Period 1 title	Baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Experimental
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	M01A H01
Investigational medicinal product code	
Other name	Celebra
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 300 mg celexocib daily for 6 weeks	
Arm title	Control
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Experimental	Control
Started	25	21
Completed	23	18
Not completed	2	3
Consent withdrawn by subject	1	2
Lost to follow-up	1	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Experimental
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	
Subject analysis set title	Statistical analysis
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The primary endpoint was feasibility. This was assessed by recruitment and retention (number of patients screened and/or consented), compliance with the intervention (based on use of celecoxib, nutritional supplements, and exercise performed), and contamination of the control arm (number of patients who tried to mimic all or part of the intervention). Feasibility of recruitment and retention was assessed by proportion of patients screened versus those consented and attrition rates.

Primary: Feasibility

End point title	Feasibility
-----------------	-------------

End point description:

The primary endpoint was feasibility. This was assessed by recruitment and retention (number of patients screened and/or consented), compliance with the intervention (based on use of celecoxib, nutritional supplements, and exercise performed), and contamination of the control arm (number of patients who tried to mimic all or part of the intervention). Feasibility of recruitment and retention was assessed by proportion of patients screened versus those consented and attrition rates. Compliance with the multimodal intervention was assessed according to individual components and thresholds of <50%, 50-80% and >80% were used. Compliance of >50% of the specific intervention in >50% of patients was considered acceptable.

End point type	Primary
----------------	---------

End point timeframe:

6 week

End point values	Experimental	Control	Statistical analysis	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	23	18	23 ^[1]	
Units: Number of patients	23	18	23	

Notes:

[1] - Only assessed in the experimental arm

Statistical analyses

Statistical analysis title	Feasibility
Comparison groups	Experimental v Statistical analysis
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	t-test, 1-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

October 3rd 2011 and until September 1st 2014.

Assessment type	Systematic
-----------------	------------

Dictionary used

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

Dictionary version	3.0
--------------------	-----

Reporting groups

Reporting group title	Experimental
-----------------------	--------------

Reporting group description:

Reported grade 3 adverse event

Serious adverse events	Experimental		
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 25 (52.00%)		
number of deaths (all causes)	25		
number of deaths resulting from adverse events	0		
Vascular disorders			
Thrombosis			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Infarction			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fever			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Neuropathy peripheral			

subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	4 / 25 (16.00%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Obstruction			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Other			
subjects affected / exposed	6 / 25 (24.00%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Experimental		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 25 (28.00%)		
Nervous system disorders			
Neutropenia			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences (all)	2		

Pain subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2		
Gastrointestinal disorders rectal bleeding subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1		
Infections and infestations Fever subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2		

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