Clinical trial results:
Placebo-controlled Evaluation of the Homeopathic Drug BRN01 for the Treatment of Hot Flashes in Women With Non Metastatic Breast Cancer Treated by Adjuvant Hormonal Therapy

Summary

EudraCT number	2009-009867-70
Trial protocol	FR
Global end of trial date	10 April 2014

Results information

Result version number	v1 (current)
This version publication date	26 January 2019
First version publication date	26 January 2019
Summary attachment (see zip file)	HBC (HBC_Support Care in Cancer 2018.pdf) HBC (HBC_NCT01246427.pdf)

Trial information

Trial identification

Sponsor protocol code	ET2008-048

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01246427
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CENTRE LEON BERARD
Sponsor organisation address	28 RUE LAENNEC, LYON, France, 69373 LYON CEDEX 08
Public contact	E. BLANC, CENTRE LEON BERARD - DIRECTION DE LA RECHERCHE CLINIQUE ET DE L'INNOVATION, DRCIreglementaire@lyon.unicancer.fr
Scientific contact	PE HEUDEL, CENTRE LEON BERARD, DRCIreglementaire@lyon.unicancer.fr

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	16 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluation of BRN01 efficacy versus placebo in reducing hot flash score after 4 weeks of treatment.

Protection of trial subjects:

Several follow-up (consultation with physician)
Provision to patient of a self-assessment booklet
Provison to patient of evaluation questionnaire
Provison to patient of satisfaction questionnaire

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 February 2010
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	France: 138
Worldwide total number of subjects	138
EEA total number of subjects	138

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)	138
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The inclusion will take place during a follow-up consultation of the patient by her oncologist, if it reports in particular BC appearing crippling, and having a negative impact on its quality of life. The investigator will verify the eligibility of the patient, inform her about the study and collect her consent to participation

Pre-assignment

Screening details:

Clinical assessment

Period 1

Period 1 title	Run-in phase
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Run in phase

Arm description:

This step is intended to select patients whose hot flashes would be particularly disabling, eliminating patients "responders" to placebo, and only retain for the rest of the trial those who could benefit from their participation.

Arm type	Selection of patient
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

oral use, tablet

Number of subjects in period 1	Run in phase
Started	138
Completed	138

Period 2

Period 2 title	Comparative evaluation phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Experimental drug
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	ACTHEANE
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 1000 mg milligram(s) per day	
Arm title	Comparative arm
Arm description: Comparative arm	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: oral use, tablet	

Number of subjects in period 2	Experimental drug	Comparative arm
Started	65	73
Completed	65	73

Baseline characteristics

Reporting groups	
Reporting group title	Run in phase

Reporting group description:

This step is intended to select patients whose hot flashes would be particularly disabling, eliminating patients "responders" to placebo, and only retain for the rest of the trial those who could benefit from their participation.

Reporting group values	Run in phase	Total	
Number of subjects	138	138	
Age categorical			
Adults >= 18 years			
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)	138	138	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Adults >= 18 years			
Units: years			
median	51		
full range (min-max)	37 to 72	-	
Gender categorical			
Units: Subjects			
Female	69	69	
Male	69	69	

End points

End points reporting groups

Reporting group title	Run in phase
Reporting group description:	
This step is intended to select patients whose hot flashes would be particularly disabling, eliminating patients "responders" to placebo, and only retain for the rest of the trial those who could benefit from their participation.	
Reporting group title	Experimental drug
Reporting group description: -	
Reporting group title	Comparative arm
Reporting group description:	
Comparative arm	

Primary: Treatment efficiency

End point title	Treatment efficiency
End point description:	
Treatment efficiency scores will be calculated as follows: (hot flash score on the 4th week of the second period)-(hot flash score on the 2nd week of the first period). Then efficiency scores will be compared between the 2 arms (placebo versus BRN01).	
End point type	Primary
End point timeframe:	
4th weeks of treatement	

End point values	Experimental drug	Comparative arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	73		
Units: score				
median (full range (min-max))	15 (10 to 57)	16 (10 to 59)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Experimental drug v Comparative arm
Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 8.6
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During all study period (inclusion to out of study)

Adverse event reporting additional description:

The Investigator immediately informs the Promoter of any serious adverse events occurring during the study in a written report, whether or not they are attributable to the research.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Adverse event

Reporting group description: -

Serious adverse events	Adverse event		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 138 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Adverse event		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 138 (2.17%)		
Musculoskeletal and connective tissue disorders			
articular event			
subjects affected / exposed	3 / 138 (2.17%)		
occurrences (all)	3		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30194492