Clinical trial results:
Prospective, randomized, controlled, open-label study evaluating quality of life in patients with advanced malignant tumors with and without “add-on” homeopathy

Summary

EudraCT number	2011-000739-97
Trial protocol	AT
Global end of trial date	20 July 2014

Results information

Result version number	v1 (current)
This version publication date	22 December 2019
First version publication date	22 December 2019
Summary attachment (see zip file)	Abstract (Abstract.docx) Publication (1-s2.0-S0965229915000370-main.pdf)

Trial information

Trial identification

Sponsor protocol code	HINC

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01509612
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Prof. Frass, Med. Univ. Wien, 0043 1404004506, michael.frass@meduniwien.ac.at
Scientific contact	Prof. Frass, Med. Univ. Wien, 0043 1404004506, michael.frass@meduniwien.ac.at

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	20 July 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 July 2014
Global end of trial reached?	Yes
Global end of trial date	20 July 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Reveal and describe the difference in QoI and SWB, in patient groups receiving standard treatment and "add on" homeopathic treatment. The null hypothesis is that "add-on" homeopathic treatment does not create a benefit for cancer patients with regard to QoL and SWB.

Protection of trial subjects:

No specific measures that were put in place to protect trial subjects.

Background therapy:

Classical conventional anti-cancer therapy in NSCLC patients

Evidence for comparator:

Comparator used in the trial was placebo in order to identify any influence of a placebo.

Actual start date of recruitment	01 September 2011
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	Austria: 150
Worldwide total number of subjects	150
EEA total number of subjects	150

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)	105
From 65 to 84 years	45
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The newly diagnosed patients are recruited at the participating centers.

Pre-assignment

Screening details:

Inclusion criteria are: Patients older than 18 years suffering from NSCLC stage IV or IIIB, IIIC diagnosed within the last 8 weeks. Exclusion criteria are: Patients not willing to sign informed consent and pregnant patients; major surgery within 4 weeks or chest irradiation wit

Period 1

Period 1 title	overall trial (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:

placebo controlled trial. no difference between verum and placebo in the physicochemical properties of the study drugs.

Arms

Are arms mutually exclusive?	Yes
Arm title	Verum

Arm description:

participants received homeopathic globules and dilutions for treatment

Arm type	Experimental
Investigational medicinal product name	Homeopathic globules and dilutions
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid, Granules
Routes of administration	Sublingual use

Dosage and administration details:

one dose daily

Arm title	placebo

Arm description:

placebo control

Arm type	Placebo
Investigational medicinal product name	Homeopathic globules and dilutions
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Granules, Oral liquid
Routes of administration	Sublingual use

Dosage and administration details:

one dose daily, placebo controle

Arm title	No Intervention arm

Arm description:

Control group for placebo and verum group

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Verum	placebo	No Intervention arm
Started	51	47	52
Completed	51	47	52

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	150	150	
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)	105	105	
From 65-84 years	45	45	
85 years and over	0	0	
Adults	0	0	
Adults_older	0	0	
Age continuous Units: years			
arithmetic mean	63.2		
standard deviation	± 8.9	-	
Gender categorical Units: Subjects			
Female	69	69	
Male	81	81	

Subject analysis sets

Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Intention to treat population was analyzed

Reporting group values	ITT		
Number of subjects	150		
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)	105		
From 65-84 years	45		
85 years and over	0		
Adults	0		
Adults_older	0		
Age continuous			
Units: years			
arithmetic mean	63.2		
standard deviation	± 8.9		
Gender categorical			
Units: Subjects			
Female	69		
Male	81		

End points

End points reporting groups

Reporting group title	Verum
Reporting group description: participants received homeopathic globules and dilutions for treatment	
Reporting group title	placebo
Reporting group description: placebo control	
Reporting group title	No Intervention arm
Reporting group description: Control group for placebo and verum group	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description: Intention to treat population was analyzed	

Primary: EORTC Quality of life

End point title	EORTC Quality of life[1]
End point description: baseline - 9 weeks - 18weeks	
End point type	Primary
End point timeframe: 18 weeks per subject	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This Endpoint was not recorded for the No-Intervention group. Only mortality was investigated for this group.

End point values	Verum	placebo	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	51	47		
Units: score				
arithmetic mean (standard deviation)	46.6 (± 25.8)	51.2 (± 28)	48.8 (± 26.8)	

Statistical analyses

Statistical analysis title	Primary Endpoint
Statistical analysis description: T-Test	
Comparison groups	Verum v placebo

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.397
Method	t-test, 2-sided

Secondary: Mortality

End point title	Mortality

End point description:

End point type	Secondary

End point timeframe:

24 months

End point values	Verum	placebo	No Intervention arm	ITT
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	47	52	150
Units: Deaths	28	36	45	109

Statistical analyses

Statistical analysis title	Verum vs. placebo
Comparison groups	Verum v placebo v ITT
Number of subjects included in analysis	248
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.02
Method	Chi-squared

Statistical analysis title	verum vs. no Intervention
Comparison groups	Verum v No Intervention arm v ITT
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared

Statistical analysis title	Placebo vs. No Intervention
Comparison groups	placebo v No Intervention arm v ITT
Number of subjects included in analysis	249
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.154
Method	Chi-squared

Statistical analysis title	Placebo and Verum vs. no intervention
Statistical analysis description: combined analysis of all subjects who received either placebo or verum versus no intervention	
Comparison groups	No Intervention arm v placebo v Verum v ITT
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Chi-squared

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

24 months

Adverse event reporting additional description:

On the basis of the investigated products (additive globules and dilutions to regular anticancer therapy) only adverse drug reactions have been recorded and documented. Adverse as such were not recorded and documented. Mortality was defined as a secondary endpoint and therefore presented in the endpoint section.

Assessment type	Non-systematic

Dictionary used

Dictionary name	ICd
Dictionary version	10

Frequency threshold for reporting non-serious adverse events: 5 %

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: As mentioned in the explanation. Based on the nature of the additives used in this trial (globules and dilution) only adverse drug reactions, but no adverse events were documented in the course of the trial. However, mortality was defined as an endpoint and is presented in the respective section.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 December 2011	Patients with high-risk mutations were excluded from participation in the trial. The No-Intervention group was added to the study design to demonstrate the possible influence of placebo treatment itself

Notes:

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.

The study duration was projected for 7 years. Recruitment was stopped thereafter.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26051564