Clinical trial results:
Phase II study of sunitinib malate (SUTENT®) in relapsed germ cell tumors in males.

Summary

EudraCT number	2007-004981-42
Trial protocol	SK
Global end of trial date	02 January 2012

Results information

Result version number	v1 (current)
This version publication date	22 September 2022
First version publication date	22 September 2022

Trial information

Trial identification

Sponsor protocol code	GCTSK001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Národný onkologický ústav
Sponsor organisation address	Klenova 1, Bratislava, Slovakia, 833 10
Public contact	Prof.Michal Mego, MD:, DSc., Narodny onkologicky ustav, 00421 259378108, michal.mego@nou.sk
Scientific contact	Prof.Michal Mego, MD:, DSc., Narodny onkologicky ustav, 00421 259378108, michal.mego@nou.sk

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	21 November 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 November 2011
Global end of trial reached?	Yes
Global end of trial date	02 January 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

12-month post treatment initiation continuous progression-free survival

Protection of trial subjects:

All the procedures performed in study involving human participants were conducted in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Background therapy:

Sunitinib malate (SUTENT®) 50 mg/day administered orally in a one daily dose for a 4 weeks in a 6 week-cycle (4 weeks on/2 weeks off)

Evidence for comparator:

NA

Actual start date of recruitment	25 July 2008
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	Slovakia: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From 25 July 2008 to October 2010, a total of 10 patients were screened into the study. 10 subjects were enrolled and receive study treatment. All patients were platinum-refractory with the excepton of one. Patients were pre-treated with a median of 3 cisplatin-containing therapies. The median age was 32 years (range 19–55 years).

Pre-assignment

Screening details:

Patients with radiological and/or serological proof of relapsed metastatic germ cell tumors, who were not eligible for curative chemotherapy or surgery and had failed at least 2 platinum-based regimens or 1 platinum regimen in the case of platinum-refractory disease or primary mediastinal non- seminomatous germ cell tumor,

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Sunitinib malate

Arm description:

Uncontrolled, Non-randomised, open-label, 1 arm (SUTENT® given orally). The single-stage Phase II design will be used.

Arm type	Experimental
Investigational medicinal product name	Sunitinib malate
Investigational medicinal product code	
Other name	SUTENT®
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Sunitinib malate (SUTENT®) 50 mg/day administered orally in a one daily dose for 4 weeks in a 6 week-cycle (4 weeks on/2 weeks off).
Administration of SUTENT® will be performed on an outpatient basis. The starting dose will be 50 mg daily. The dose should be taken once daily at approximately the same time of day. Patients are required to have a drug rest period of at least 14 days after each dosing period. The start of the next cycle may be delayed if additional time is required for the patient to recover from treatment-associated toxicity experienced during the previous cycle. Dosing may be modified after discussion with Principal Investigator. The study investigator implements dose suspension or reduction in order to ensure patient safety. No pre-medication or patient monitoring immediately after administration of SUTENT is required.

Number of subjects in period 1	Sunitinib malate
Started	10
Completed	10

Baseline characteristics

Reporting groups

Reporting group title	Overall Study (overall period)

Reporting group description:

Single arm trial with Sunitinib malate (SUTENT®) 50 mg/day administered orally.

Reporting group values	Overall Study (overall period)	Total	
Number of subjects	10	10	
Age categorical			
male subjects from 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)	10	10	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
The median age was 32 years (range 19–55 years).			
Units: years			
arithmetic mean	32		
full range (min-max)	19 to 55	-	
Gender categorical			
male subjects			
Units: Subjects			
Female	0	0	
Male	10	10	

Subject analysis sets

Subject analysis set title	Overall study (overall period)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Single arm trial with Sunitinib malate (SUTENT®) 50 mg/day administered orally.

Reporting group values	Overall study (overall period)		
Number of subjects	10		
Age categorical			
male subjects from 18 years.			
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)	10		
From 65-84 years	0		
85 years and over	0		
Age continuous			
The median age was 32 years (range 19–55 years).			
Units: years			
arithmetic mean	32		
full range (min-max)	19 to 55		
Gender categorical			
male subjects			
Units: Subjects			
Female	0		
Male	10		

End points

End points reporting groups

Reporting group title	Sunitinib malate

Reporting group description:

Uncontrolled, Non-randomised, open-label, 1 arm (SUTENT® given orally). The single-stage Phase II design will be used.

Subject analysis set title	Overall study (overall period)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Single arm trial with Sunitinib malate (SUTENT®) 50 mg/day administered orally.

Primary: Twelve-month post treatment initiation continuous progression-free survival rate (intent-to-treat population)

End point title	Twelve-month post treatment initiation continuous progression-free survival rate (intent-to-treat population)

End point description:

Twelve month post-treatment initiation continuous progression-free survival rate will be summarized as counts and proportions with exact binomial 90% confidence interval (ITT population)

End point type	Primary

End point timeframe:

PFS will be calculated from the starting the treatmentl to the date of progression or death or or to the date of last follow up.

End point values	Sunitinib malate	Overall study (overall period)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10[1]	10[2]		
Units: weeks				
number (not applicable)	10.8	10.8		

Notes:

[1] - Median Progression-free survival was 10.8 weeks

[2] - Median Progression-free survival was 10.8 weeks

Statistical analyses

Statistical analysis title	descriptive statistics
Comparison groups	Sunitinib malate v Overall study (overall period)
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	other[3]
P-value	< 5
Method	Chi-squared

Notes:

[3] - Intention to treat analysis.

Secondary: Overall response rate

End point title	Overall response rate

End point description:

Overall response rate = rate of complete remission (CR) or partial response (PR) based on RECIST criteria among all evaluable patients

End point type	Secondary

End point timeframe:

Objective response rate is defined as sum of complete and partial responses. It is defined from start of the treatment until progresson of disease or start of new anticancer treatment.

End point values	Sunitinib malate	Overall study (overall period)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10[4]	10[5]		
Units: number of patients	2	2		

Notes:

[4] - 2 patients achieved PR, 0 CR

[5] - 2 patients achieved PR, 0 CR

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response

End point title	Duration of response

End point description:

Response Duration will be measured from the time when measurement criteria for CR/PR (whichever is first recorded) are first met until the first date that recurrent or progressive disease is objectively documented, taking as reference the smallest measurements recorded since the treatment started.

End point type	Secondary

End point timeframe:

Duration of response (CR+PR), defined from the earliest time when confirmed remission criteria are met until death or progression. Patients continuing in remission at the end of the study are treated as censored (ITT population).

End point values	Sunitinib malate	Overall study (overall period)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10[6]	10[7]		
Units: weeks				
number (not applicable)	10.2	10.2		

Notes:

[6] - Duration of response was 10,2 weeks (71,5 days)

[7] - Duration of response was 10,2 weeks (71,5 days)

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival

End point description:

The length of time from the start of treatment to to the death.

End point type	Secondary

End point timeframe:

Overall survival (OS) will be calculated from the beginning of the treatment until death from any cause on intention-to-treat basis.

End point values	Sunitinib malate	Overall study (overall period)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10[8]	10[9]		
Units: weeks				
arithmetic mean (standard deviation)	12.9 (± 0.1)	12.9 (± 0.1)		

Notes:

[8] - Overall survival was 12,9 weeks.

[9] - Overall survival was 12,9 weeks.

Statistical analyses

No statistical analyses for this end point

Secondary: Toxicity

End point title	Toxicity

End point description:

For evaluation of toxicity, NCI Common Terminology Criteria for Adverse Events Version 3.0 (CTCAE) was used.

End point type	Secondary

End point timeframe:

Toxicity will be evaluated in all patients from the time of first administration of the Sutent®.

End point values	Sunitinib malate	Overall study (overall period)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	10[10]	10[11]		
Units: number of patients and events	4	4		

Notes:

[10] - 4 subjects experienced at least one adverse event Gr.3 or 4.

[11] - 4 subjects experienced at least one adverse event Gr.3 or 4.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events will be evaluated in all patients from the time of first administration of the Sutent® on an ongoing basis.

Adverse event reporting additional description:

Adverse events will be categorized using the CTCAE, Version 3.0. The worst event for each patient will be described. Both events related and unrelated to treatment will be captured. Clinical and laboratory data will be tabulated and compared to normal ranges for the institution.
Adverse events Grade 3 and Grade 4 will be reported.

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	3.0

Reporting groups

Reporting group title	all subjects

Reporting group description: -

Serious adverse events	all subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	8		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	all subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 10 (40.00%)		
Investigations			
Thrombocytopenia	Additional description: 2 subjects experienced Thrombocytopenia, Gr.3.		
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia	Additional description: 1 subject experienced Anaemia, Gr.3		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Gastrointestinal disorders			

Nausea	Additional description: 1 subject experienced Nausea, Gr.4.		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Vomiting	Additional description: 1 subject experienced Vomiting, Gr.4.		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		

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/22846980