1. Trial Information

1.1 Sponsor details

EudraCT number	2021-001059-15
Full title of the trial	English: The value of 99mTc-MIP-1404 SPECT/CT Veriton CZT for staging of prostate cancer and before primary therapy and in biochemical recurrence after radical prostatectomy. Swedish: Rollen av 99mTc-MIP-1404 SPECT/CT Veriton CZT för stadieindelning av Prostata Cancer inför primär terapi och vid biokemisk återfall efter radikal prostatektomi.
Responsible researcher (point of contact) - Name - Email address	- Miguel Ochoa Figueroa - Miguel.ochoa.figueroa@regionostergotland.se - Migue8a@hotmail.com -

1.2 Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	☐Yes	☒No
- If yes, enter EMA paediatric investigation plan (EMEA PIP code)		
Does article 45 of Regulation (EC) No 1901/2006 apply to this trial?	☐Yes	☒No
Does article 46 of Regulation (EC) No 1901/2006 apply to this trial?	☐Yes	☒No

1.3 Results analysis stage

Date of interim/final analysis (dd/mm/yy):	31/12/2024	
Is this the analysis of the primary completion data?	☒Yes	☐No
Primary completion date (dd/mm/yy):	23/12/2024	

(The primary completion date is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary end point.)		
Global end of trial date reached? *(The global end of trial date is when the last subject in the trial was examined or received an intervention globally.)*	☒Yes	☐No
	Date (dd/mm/yy): 17/12/2024	
Was the trial ended prematurely?	☒Yes	☐No

1.4 General information about the trial

Actual start date of recruitment (dd/mm/yy):	16-01-03	
Long term follow-up planned?	☐Yes	☒No
- If yes, enter rationale (Select main reason(s) for long-term follow up)	☐Safety ☐Efficacy ☐Ethical reason ☐Regulatory reason ☐Scientific research	
Long term follow-up duration (number of months/years)		
Independent data monitoring committee (IDMC) involvement?	☐Yes	☒No

1.5 Population of trial subjects

Subject number per country	
Country	**Actual number of subjects enrolled**
a) Sweden b) c)	a) 74 b) c)
Age group breakdown for trial	
Age range	**Actual number of subjects enrolled**
In utero	

Preterm newborn infants (gestational age < 37 wks)	
Newborns (0-27 days)	
Infants and toddlers (28 days-23 months)	
Children (2-11 years)	
Adolescents (12-17 years)	
Adults (18-64 years)	74
From 65-84 years	
85 years and over	

2. Subject Disposition

2.1 Period details

Allocation method (choose one)	☐Randomized – controlled ☐Non-randomized – controlled ☒Not applicable
Blinding used (choose one)	☐Double blind ☐Single blind ☒Not blinded
- If blinded, choose roles that were blinded	☐Subject ☐Investigator ☐Monitor ☐Data analyst ☐Carer ☐Assessor

2.2 Arm Information

Total number of study arms	1

Arm 1:

Arm Title	The value of 99mTc-MIP-1404 SPECT/CT Veriton CZT for staging of prostate cancer and before primary therapy and in biochemical recurrence after radical prostatectomy.
Arm type (choose one)	☐Experimentell

	☒Active comparator ☐Placebo ☐No intervention ☐Other
Number of subjects started:	74
Number of subjects completed:	64
Subject non-completion reason	
Reason	Number of subjects
a) ☐Adverse event, non-fatal b) ☐Adverse event, serious fatal c) ☐Consent withdrawn by subject d) ☐Lack of efficacy e) ☒Lost to follow-up f) ☒Physician decision g) ☐Pregnancy h) ☐Protocol deviation i) ☐Transferred to another arm/group j) ☐Other (please specify)	a) b) c) d) e) 5 f) 5 g) h) i) j)
Subject joining reason	
Number of subjects	
Reason	☐Late recruitment ☐Transferred from another arm/group ☐Other (please specify)

Arm 2 (only fill in if a 2nd arm was used in the study):

Arm Title	
Arm type (choose one)	☐Experimentell ☐Active comparator ☐Placebo ☐No intervention ☐Other
Number of subjects started:	

Number of subjects completed:	
Subject non-completion reason	
Reason	Number of subjects
a) ☐Adverse event, non-fatal b) ☐Adverse event, serious fatal c) ☐Consent withdrawn by subject d) ☐Lack of efficacy e) ☐Lost to follow-up f) ☐Physician decision g) ☐Pregnancy h) ☐Protocol deviation i) ☐Transferred to another arm/group j) ☐Other (please specify)	a) b) c) d) e) f) g) h) i) j)
Subject joining reason	
Number of subjects	
Reason	☐Late recruitment ☐Transferred from another arm/group ☐Other (please specify)

Arm 3 (only fill in if a 3rd arm was used in the study):

Arm Title	
Arm type (choose one)	☐Experimentell ☐Active comparator ☐Placebo ☐No intervention ☐Other
Number of subjects started:	
Number of subjects completed:	
Subject non-completion reason	
Reason	Number of subjects
a) ☐Adverse event, non-fatal b) ☐Adverse event, serious fatal	a) b)

c) ☐Consent withdrawn by subject d) ☐Lack of efficacy e) ☐Lost to follow-up f) ☐Physician decision g) ☐Pregnancy h) ☐Protocol deviation i) ☐Transferred to another arm/group j) ☐Other (please specify)	c) d) e) f) g) h) i) j)
Subject joining reason	
Number of subjects	
Reason	☐Late recruitment ☐Transferred from another arm/group ☐Other (please specify)

3. Baseline Characteristics

Age and gender are always included as baseline characteristics. Are there other study specific baseline characteristics you would like to report?	☐Yes	☒No
- If yes, which baseline characteristics - Where in your published article can these be found? (e.g. Table 1, column X, row Y)	- -	

4. End point definition

Please describe the primary end points that answer the main objective. Please also provide information on where in your published article these results can be found (e.g. Table X, column Y, row Z).

End point 1:

End point title	Accuracy of 99mTc-MIP-1404 SPECT/CT Veriton CZT compared with conventional radiology and Ga68-PSMA PET/CT in identifying lymph node and bone metastases in primary staging of high-risk PCa and in BCR after RP

End point type	☒Primary ☐Secondary ☐Other pre-specified ☐Post-hoc		
Data can be found here: *(Numerical raw data e.g. mean ± SD, median and IQR/ min-max range)*	Table	Row	Column
	Article under review, manuscript attached. Another article is under preparation.		
Statistical Analysis			
Statistical Analysis Title: (e.g. "Difference in XXX")	Sensitivity and specificity of 99mTc-MIP-1404 SPECT/CT,		
Comparison groups (which arms should be compared)	99mTc-MIP-1404 SPECT/CT, Ga68-PSMA PET/CT, Computed tomography, Bone scan		
Analysis specification	☒Pre-specified	☒Post-hoc	
Analysis type	☐Non-inferiority ☐Equivalence ☒Superiority ☐Other (specify)		
Statistical analysis method:	☐ANCOVA ☒ANOVA ☒Chi-squared ☐Chi-squared, corrected ☐Cochran-Mantel-Haenszel ☐Fisher exact ☐Kruskal-wallis ☐Logrank ☐Mantel-Haenszel ☐Mcnemar ☐Mixed models analysis ☐Regression, Cox		

	☐Regression, Linear ☐Regression, Logistic ☐Sign test ☐t-test, 1-sided ☐t-test, 2-sided ☐Wilcoxon (Mann-Whitney) ☐Other (please specify)

End point 2 (Optional):

End point title			
End point type	☐Primary ☐Secondary ☐Other pre-specified ☐Post-hoc		
Data can be found here: *(Numerical raw data e.g. mean ± SD, median and IQR/ min-max range)*	Table	Row	Column
Statistical Analysis			
Statistical Analysis Title: (e.g. "Difference in XXX")			
Comparison groups (which arms should be compared)			
Analysis specification	☐Pre-specified	☐Post-hoc	
Analysis type	☐Non-inferiority ☐Equivalence ☐Superiority ☐Other (specify)		
Statistical analysis method:	☐ANCOVA ☐ANOVA ☐Chi-squared ☐Chi-squared, corrected ☐Cochran-Mantel-Haenszel ☐Fisher exact ☐Kruskal-wallis ☐Logrank		

	☐Mantel-Haenszel ☐Mcnemar ☐Mixed models analysis ☐Regression, Cox ☐Regression, Linear ☐Regression, Logistic ☐Sign test ☐t-test, 1-sided ☐t-test, 2-sided ☐Wilcoxon (Mann-Whitney) ☐Other (please specify)

End point 3 (Optional):

End point title			
End point type	☐Primary ☐Secondary ☐Other pre-specified ☐Post-hoc		
Data can be found here: *(Numerical raw data e.g. mean ± SD, median and IQR/ min-max range)*	Table	Row	Column
Statistical Analysis			
Statistical Analysis Title: (e.g. "Difference in XXX")			
Comparison groups (which arms should be compared)			
Analysis specification	☐Pre-specified	☐Post-hoc	
Analysis type	☐Non-inferiority ☐Equivalence ☐Superiority ☐Other (specify)		
Statistical analysis method:	☐ANCOVA ☐ANOVA ☐Chi-squared ☐Chi-squared, corrected		

	☐Cochran-Mantel-Haenszel ☐Fisher exact ☐Kruskal-wallis ☐Logrank ☐Mantel-Haenszel ☐Mcnemar ☐Mixed models analysis ☐Regression, Cox ☐Regression, Linear ☐Regression, Logistic ☐Sign test ☐t-test, 1-sided ☐t-test, 2-sided ☐Wilcoxon (Mann-Whitney) ☐Other (please specify)

5. Adverse events

5.1 Overview

Timeframe for adverse event reporting (Enter the time point(s) or time period for adverse events assessment)	None	
Assessment type	☐Systematic	☐Non-systematic
Adverse events dictionary name	☐MedDRA ☐SNOMED CT ☐Other (specify):	
Dictionary version		

5.2 Adverse event reporting

Summary

How do you wish to report adverse events?	☐Per arm	☒For all study subjects
Number of subjects affected by serious adverse events	None	
Number of subjects affected by non-serious adverse events	None	

Total number of deaths (all causes)	None
Total number of deaths resulting from adverse events	None

Serious adverse event details and values (Only needed if serious adverse events were reported)

System organ class	Number of subjects	Event Term (i.e. headache, nausea etc)	Occurrences
a) ☐ Blood and lymphatic system disorders	a)	a)	a)
b) ☐ Cardiac disorders	b)	b)	b)
c) ☐ Congenital, familial and genetic disorders	c)	c)	c)
d) ☐ Ear and labyrinth disorder	d)	d)	d)
e) ☐ Endocrine disorders	e)	e)	e)
f) ☐ Eye disorders	f)	f)	f)
g) ☐Gastrointestinal disorders	g)	g)	g)
h) ☐General disorders and administration site conditions	h)	h)	h)
i) ☐Hepatobiliary disorders	i)	i)	i)
j) ☐Immune system disorders	j)	j)	j)
k) ☐Infections and infestations	k)	k)	k)
l) ☐Injury, poisoning and procedural complications	l)	l)	l)
m) ☐Investigations	m)	m)	m)
n) ☐Metabolism and nutrition disorders	n)	n)	n)
o) ☐Musculoskeletal and connective tissue disorders	o)	o)	o)
p) ☐Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	p)	p)	p)
q) ☐Nervous system disorders	q)	q)	q)

r) ☐Pregnancy, puerperium and perinatal conditions s) ☐Product issues t) ☐Psychiatric disorders u) ☐Renal and urinary disorders v) ☐Reproductive system and breast disorders w) ☐Respiratory, thoracic and mediastinal disorders x) ☐Skin and subcutaneous tissue disorders y) ☐Social circumstances z) ☐Surgical and medical procedures aa) ☐Vascular disorders	r) s) t) u) v) w) x) y) z) aa)	r) s) t) u) v) w) x) y) z) aa)	r) s) t) u) v) w) x) y) z) aa)
Assessment type	☐Systematic	☐Non-systematic	

Non-serious adverse event details and values (Only needed if non-serious adverse events were reported)

System organ class	Number of subjects	Event Term (i.e. headache, nausea etc)	Occurrences
a) ☐ Blood and lymphatic system disorders b) ☐ Cardiac disorders c) ☐ Congenital, familial and genetic disorders d) ☐ Ear and labyrinth disorder e) ☐ Endocrine disorders f) ☐ Eye disorders g) ☐Gastrointestinal disorders h) ☐General disorders and administration site conditions i) ☐Hepatobiliary disorders	a) b) c) d) e) f) g) h) i)	a) b) c) d) e) f) g) h) i)	a) b) c) d) e) f) g) h) i)

j) ☐Immune system disorders k) ☐Infections and infestations l) ☐Injury, poisoning and procedural complications m) ☐Investigations n) ☐Metabolism and nutrition disorders o) ☐Musculoskeletal and connective tissue disorders p) ☐Neoplasms benign, malignant and unspecified (incl. cysts and polyps) q) ☐Nervous system disorders r) ☐Pregnancy, puerperium and perinatal conditions s) ☐Product issues t) ☐Psychiatric disorders u) ☐Renal and urinary disorders v) ☐Reproductive system and breast disorders w) ☐Respiratory, thoracic and mediastinal disorders x) ☐Skin and subcutaneous tissue disorders y) ☐Social circumstances z) ☐Surgical and medical procedures aa) ☐Vascular disorders	j) k) l) m) n) o) p) q) r) s) t) u) v) w) x) y) z) aa)	j) k) l) m) n) o) p) q) r) s) t) u) v) w) x) y) z) aa)	j) k) l) m) n) o) p) q) r) s) t) u) v) w) x) y) z) aa)
Assessment type	☐Systematic	☐Non-systematic	

6. More information

Were there any global substantial amendments to the protocol?	☐Yes	☒No
- If yes, please provide Amendment date - If yes, please provide Amendment description	- -	
Were there any global interruptions to the trial?	☐Yes	☒No
- If yes, please provide Interruption date - If yes, please provide Interruption description - If yes, please provide Restart date (if applicable)	- - -	