Clinical trial results:
Vascular Targeted Photodynamic therapy with WST11 for T1a Renal Tumours. PHASE IIa histological follow up trial

Summary

EudraCT number	2011-003311-27
Trial protocol	GB
Global end of trial date	11 February 2017

Results information

Result version number	v1 (current)
This version publication date	15 February 2019
First version publication date	15 February 2019
Summary attachment (see zip file)	VTPfinalreport (final_report_templateVTP2 (3).docx)

Trial information

Trial identification

Sponsor protocol code	CLIN1102KCM201

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of Oxford
Sponsor organisation address	Old Road, Oxford, United Kingdom,
Public contact	Tom Leslie, Nuffield Department of Surgical Sciences, University of Oxford, tom.leslie@nds.ox.ac.uk
Scientific contact	Tom Leslie, Nuffield Department of Surgical Sciences, University of Oxford, tom.leslie@nds.ox.ac.uk

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	22 September 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 February 2017
Global end of trial reached?	Yes
Global end of trial date	11 February 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate efficacy of VTP treatment as assessed by histology in T1a Renal Tumours

Protection of trial subjects:

General anaesthetic given for procedure to prevent pain and post-operative pain relief as required. Eye protection immediately post treatment to prevent eye problems in natural light.

Background therapy:

None

Evidence for comparator: -

Actual start date of recruitment	04 June 2012
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	United Kingdom: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	2
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening details included a history and clinical examination, performed by a trial enrolled doctor. The Trial nurse went through inclusion and exclusion criteria. Blood tests including a full blood count, urea and electrolytes and liver function tests were performed together with an electrocardiogram. CT or MRI showing a renal mass was confirmed

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not relevant

Arms

Arm title	single arm

Arm description:

Treatment of renal tumour with WST11

Arm type	Experimental
Investigational medicinal product name	WST11
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Intravenous bolus use

Dosage and administration details:

Prepared infusion. Dosage given as 2mgs/kg or 4mgs/kg as per trial protocol. Single dosage

Number of subjects in period 1	single arm
Started	5
Completed	5

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	5	5	
Age categorical Units: Subjects			
Adults (18-64 years)	2	2	
From 65-84 years	3	3	
Gender categorical Units: Subjects			
Female	3	3	
Male	2	2	

End points

End points reporting groups

Reporting group title	single arm
Reporting group description:	
Treatment of renal tumour with WST11	

Primary: Extent of necrosis in renal tumour histologically

End point title	Extent of necrosis in renal tumour histologically[1]
End point description:	
The end point used was to assess tumour cell death caused by the trial treatment	
End point type	Primary
End point timeframe:	
Necrosis was measured histologically in the surgical specimen (partial or radical nephrectomy) which was performed approximately 4 weeks following the VTP treatment	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Histological analysis based on microscopic assessment, n = 5 and unable to do any meaningful statistical analysis on this	

End point values	single arm			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: percentage necrosis in whole tumour				
number (not applicable)				
Percentage necrosis in tumour following treatment	27.0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From VTP treatment until 18 months post VTP treatment

Adverse event reporting additional description:

Collected as per CTCAE definition. Cases assessed on day 1,2 and 12 following the VTP treatment. Further assessment was made based on individual adverse events and included 1 referral to an Opthalmologist regarding eye symptoms, follow up of a urine leak radiologically and a completion nephrectomy.

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.03

Reporting groups

Reporting group title	APTIV

Reporting group description: -

Serious adverse events	APTIV		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 5 (20.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Surgical and medical procedures			
Surgical failure	Additional description: Unable to locate tumour correctly following VTP treatment. Initial attempt at partial nephrectomy based on apparently ablated tissue but normal tissue excised and second operation to remove whole kidney required to excise tumour		
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	APTIV		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)		
Surgical and medical procedures			
Urine leak	Additional description: I case leaked urine following the partial nephrectomy. This is a recognised complication of a standard partial nephrectomy but it is not clear if the ablation may have increased the risk of this		
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		

Eye disorders			
blurred vision and irritated eyes	Additional description: Both settled spontaneously though Opthalmology opinion requested for eye irritation		
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 April 2015	The recruitment period was extended by 12 months. The number of cases to recruit was reduced from 12 to 8 and the lower age threshold for recruitment was reduced from 60 to 50

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.

Early termination due to slow recruitment. leading to a smaller number than intended subjects for analysis together with the inability of MRI scanning post treatment to demonstrate the ablation zone

Notes: