WIN-O Renal Cell Carcinoma Nivolumab Registry (RCCNR)

Bij patiënten met een gemetastaseerd niercelcarcinoom die worden behandeld met nivolumab is goede registratie erg belangrijk voor de evaluatie van bijwerkingen en effectiviteit. Hiervoor moet onderstaande schema gevolgd worden. Dit hoort bij standaard zorg van deze behandeling. Graag alles in EPD of status van patiënt vermelden zodat dit later terug gevonden kan worden. De radiologische evaluatie, performance van patiënt, laboratoriumonderzoek bij de start zijn zeer essentieel voor toekomstige analyses. Lichamelijk onderzoek, vitale functies e.d. kunnen volgens lokaal gebruik plaats vinden.

Table 1: *Timing of different procedures during treatment phase.*

	Screening	Treatment phase									
Treatment cycle		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**9**	**11**	Cont.
Week	*-3 – 0*	*0*	*2*	*4*	*6*	*8*	*10*	*12*	*16*	*20*	Cont.
Administrative Procedures											
Age, Gender	X										
RCC history[1]	X										
Concomitant medication	X	X	X	X	X	X	X	X	X	X	Cont.
Dose Nivolumab		X	X	X	X	X	X	X	X	X	Cont.
Clinical Procedures											
Adverse events (CTCAE v. 4.0)[2]	X	X	X	X	X	X	X	X	X	X	Cont.
WHO performance	X	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	Cont.
Laboratory Procedures											
CBC	X	X	X	X	X	X	X	X	X	X	Cont.
WBC differential	X	X	X	X	X	X	X	X	X	X	Cont.
Serum chemistry[3]	X	X	X	X	X	X	X	X	X	X	Cont.
CRP, ESR	X										Cont.
fT3, fT4, TSH, LH, ACTH, cortisol, testosterone, estradiol	X	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	X[6]	Cont.
TSH				X		X		X	X	X	
Response assessment											
Tumor imaging[4]	X							X	X[7]		Cont. per 6 cycles
Biopsy											
Tumor biopsies [5]	X (and at PD)										

1: Date of nephrectomy, histology of tumor, site of metastases at date of inclusion, date first systemic treatment for metastatic disease, prior systemic treatments, location metastases at date of inclusion.
2: All drug-related adverse events (AE's) should be noted. AE's of special interest are: hypothyroidism, pneumonitis, vitiligo, uveitis, arthritis, colitis, dermatitis, hypophysitis, hepatitis.
3: This should include at least: LDH, Creat, ALT, ALP, Total Bili, Ca, Alb, glucose.
4: Response should be assessed according to RECIST 1.1 and if possible according to immune-related response criteria. Screening assessment should include thoracic, abdominal and pelvic. CT Brain MRI/CT is only necessary when brain metastases were present at screening, or on clinical indication.
5: Optional and if possible also in case of disease progression (CPCT-study). For future studies a FFPE tumor block could be used for PD-L1 immunohistochemistry.
6: could be considered or if indicated

7: could be considered in case of stable disease or progressive disease at week 12