Study details

Name of the reviewer

Study details

Name	Duration of trial	Settings	Comparisons
Name and year of the study			Intervention versus Comparators

Study aim:

Study design:

Dosing:
Dose of intervention:
Dose of control:
Dose of any other treatments:
Intervention in both groups:

Definition of SRE:

Methods of assessment of SREs during follow-up:

Primary outcomes:

Other outcomes:

Follow-up:

Safety data:

Inclusion criteria:

Exclusion criteria:

Previous treatment

Patient characteristics

No. of patients, *n* (%)	Intervention (*n*=)	Control (*n*=)
Screened		
Excluded		
Enrolled		
Randomised		
Excluded		
Efficacy analysis		
Safety analysis		
Discontinued		
Primary data analysis cut-off date		
Patient characteristics	Intervention (*n*=)	Control (*n*=)
Total patients, *n*		
Age (years)		
Sex (M/F), *n* (%)		
Ethnicity, *n* (%)		
White		
Other		
ECOG performance status 0–1, *n* (%)		
Time from diagnosis of prostate cancer to randomisation (months/years)		
Time from diagnosis of bone metastases to randomisation (months/years)		
Presence of visceral metastases, *n* (%)		
Recent chemotherapy, *n* (%)		
Haemoglobin concentration (g/l), mean (SD)		
Creatinine clearance of ≥1.5 ml/second, *n* (%)		
PSA at randomisation (μg/l)		
<10, *n* (%)		
≥10, *n* (%)		
Gleason score at diagnosis, *n* (%)		
2–6		
7		
8–10		
Missing		
Bone turnover markers, median (IQR)		
BSAP (μg/l)		
Urinary N-telopeptide (nmol/mmol)		
Previous SREs, *n* (%)		

Quality of the study

Quality of the study	Details	Yes/No/Unclear
Adequate sequence generation		
Allocation concealment		
Blinding		
Incomplete outcome data addressed		
Free of selective reporting		
Generalisability		
Sample size calculation		
Conflict of interest		
Source of funding		

Outcomes and safety

	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups (95% CI)**	***p*-value**
Time to first on-study SREs (in months/years)				
	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups (95% CI)**	***p*-value**
Time to first and subsequent on-study SREs				
Number of events				
	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups**	***p*-value**
Number of patients with first on-study SREs, *n* (%)				
Total confirmed events				
Radiation to bone				
Pathological fracture				
SCC				
Surgery to bone				
	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups**	***p*-value**
Overall survival rate				
	Intervention (*n*=)	**Control (*n*=)**		
SMR (the ratio of the number of skeletal complications to the time on trial)				
	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups**	***p*-value**

Time to disease progression				
	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups**	***p*-value**
HRQoL				
	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups**	***p*-value**
Any adverse events, *n* (%)				
Acute-phase reactions, *n* (%)				
Adverse events associated with renal impairments, *n* (%)				
Withdrawals due to adverse events, *n* (%)				
Reasons for withdrawal				
Death				
Disease progression				
Consent withdrawn				
Adverse events				
Patient request				
Lost to follow-up				
Non-compliance				
Administrative decision				
Protocol deviation				
Ineligibility determined				
Other				
	Intervention (*n*=)	**Control (*n*=)**	**Difference between groups**	***p*-value**
CTCAE grade 3 or 4 adverse events				
Adverse events occurring with ≥20% frequency in either treatment group, *n* (%)				
Back pain				
Pain in extremity				
Bone pain				
Arthralgia				
Asthenia				
Anaemia				
Decreased appetite				
Nausea				
Fatigue				
Constipation				
Peripheral oedema				
Infectious adverse events, *n* (%)				
Cumulative ONJ (total)				

Year 1
Year 2
Hypocalcaemia
SAEs
Fatal adverse events
New primary malignant disease