

This dictionary file is for Dataset NCT01863550-D1-Dataset.csv

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

This dataset corresponds to information in Lancet Oncol. 2020 Oct; 21(10): 1317-1330

[PMC7591827](#)

Note: Unless otherwise specified, blank values indicate missing data or not applicable.

Dataset description: Clinical information

Observations: 1087

Variables: 48

List of Variables and Attributes

#	Variable	Type	Description	Code
1	case	Num	A blinded ID generated by ECOG-ACRIN	
2	arm_s1	Num	Step 1 (S1) arm assignment	1=A: VRd, 2=B: KRd
3	elig	Char	Eligibility Status	No, Questionable, Yes
4	inelig_reas_class	Num	Reason excluded	1=Baseline labs inadequate, 2=No measurable disease, 3=FISH not done or evidence High Risk, 4=Uncontrolled intercurrent infection, 5=Previous treatment within 14 days, 6=Baseline laboratory levels outside cutoff, 7=Exceeded dex dose
5	start_s1	Num	Started assigned treatment S1	1=No, 2=Yes
6	offtx_reas	Num	Reason off-treatment S1	1=Treatment completed, 2=PD, 3=AE, 4=Death, 5=W/D, 6=Alternative therapy, 7=Other complicating disease, 8=Non-Compliance, 9=MD Decision, 10=Insurance Issue, 11=Ineligible, 12=Moved, 13=Treatment Held Too Long, 88=Other,

				99=Unknown
7	arm_s2	Num	Step 2 (S2) arm assignment	1=C: R Ltd, 2=D: R Indef
8	age	Num	Age at randomization	In years
9	timefromdiag	Num	Time of randomization from diagnosis	In weeks
10	sex	Num	Sex	0=Female, 1=Male
11	race	Char	Race	White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Not Reported, Unknown
12	ecogps	Num	ECOG performance status	0=0, 1=1, 2=2, 3=3
13	sctintent	Num	Intention to transplant at disease progression	1=No Intent SCT at PD, 2=Yes Intent SCT at PD
14	iss	Num	International Staging System	1=I, 2=II, 3=III
15	measdz	Char	Measurable disease type	BM: Bone marrow plasmacytosis, FLC: Free light chain, SPEP, SPEP&UPEP, UPEP, Not Measurable
16	cytogen	Num	Cytogenetics	1=Normal, 2=Abnormal
17	fish	Num	Fluorescence in situ hybridisation	1=Normal, 2=Abnormal
18	plasma	Num	Circulating plasma cells	In percentage
19	albumin	Num	Serum albumin concentration	In g/dL
20	b2m	Num	Serum beta-2-microglobulin concentration	In µg/mL
21	hgb	Num	Serum haemoglobin concentration	In g/dL
22	calcium	Num	Serum calcium concentration	In mg/dL
23	creat	Num	Creatinine Status	In mg/dL; 0=0-2, 1=GE 2

24	ldh	Num	Lactate Dehydrogenase	In U/L; 0=0-190, 1=GE 190
25	fish_13q	Num	13q Status	0=Absent, 1=Present
26	fish_t414	Num	t(4;14) Status	0=Absent, 1=Present
27	fish_t1114	Num	t(11;14) Status	0=Absent, 1=Present
28	txdur_s1	Num	Duration of induction therapy	In months
29	sct	Num	SCT status	1=SCT: No, 2=SCT: Yes
30	t2sct	Num	Time to SCT from randomization	In months
31	bestresp	Num	Best overall response in S1	1=sCR, 2=CR, 3=VGPR, 5=PR, 6=SD, 7=PD, 8=Unevaluable, 9=Insufficient
32	mrdneg	Num	MRD negativity at week 36	0=MRD Neg CR: No, 1=MRD Neg CR: Yes
33	earlyresp	Num	Response within 12 weeks	1=sCR, 2=CR, 3=VGPR, 5=PR, 6=SD, 7=PD, 8=Unevaluable, 9=Insufficient
34	t2resp	Num	Time to first at least partial response	In months
35	t2pfs	Num	Progression-Free Survival (primary)	In months
36	c4pfs	Num	Censor for PFS	0=Event, 1=Censored
37	t2surv	Num	Overall Survival (primary)	In months
38	c4surv	Num	Censor for OS	0=Event, 1=Censored
39	t2pfs_sens2	Num	PFS Sensitivity: All deaths counted as event	In months

40	c4pfs_sens2	Num	Censor for PFS sensitivity: all deaths counted as event	0=Event, 1=Censored
41	t2pfs_sens3	Num	PFS Sensitivity: Censor at time of SCT or alternative therapy	In months
42	c4pfs_sens3	Num	Censor for PFS sensitivity: censor at time of SCT or alternative therapy	0=Event, 1=Censored
43	t2pfs_sens4	Num	PFS Sensitivity: Censor at time of last contact	In months
44	c4pfs_sens4	Num	Censor for PFS sensitivity: censor at time of last contact	0=Event, 1=Censored
45	t2prog	Num	Time to Progression	In months
46	c4prog	Num	Censor for Time to Progression	0=Event, 1=Censored
47	death_aers	Char	Lethal AE per AERS	
48	death_aersrel	Char	Lethal AE per AERS treatment relation	No, Yes Note: For lethal AEs per AERS, the treatment relation is determined by the safety Principle investigators as opposed to AE CRF wherein sites report treatment attribution.