

# Real-world outcomes of advanced melanoma patients not represented in phase III trials

**R.K. Ismail\***, M.C.T. van Zeijl, L.C. de Wreede, A.J.M. van den Eertwegh, A. de Boer, M. van Dartel, D.L. Hilarius, M.J.B. Aarts, F.W.P.J. van den Berkmoortel, M.J. Boers-Sonderen, J.W.B. de Groot, G.A.P. Hospers, E. Kapiteijn, D. Piersma, R.S. van Rijn, K.P.M. Suijkerbuijk, A.J. ten Tije, A.A.M. van der Veldt, G. Vreugdenhil, J.B.A.G. Haanen, M.W.J.M. Wouters

## Background

Real-world patients not fulfilling the phase III RCT inclusion criteria (ineligible patients) are being treated without evidence of the efficacy and safety in daily clinical practice.

## Objective

To provide evidence on clinical outcomes of systemically treated patients with advanced melanoma not represented in phase III trials to support clinical decision-making.

## Patients and Methods

- Advanced melanoma patients (diagnosed between 2014-2017)
- Systemically treated ineligible patients
  - Exclusion criteria derived from KEYNOTE-006 and CHECKMATE-067/-066 phase III trials
- Analysis: Descriptive statistics, Kaplan-Meier estimates, Cox models, Survival decision tree

## Results

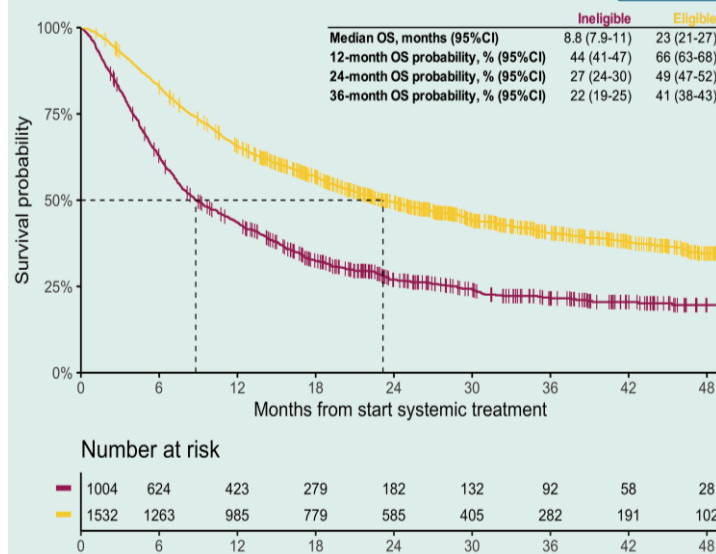


Figure 1: Survival of ineligible (purple curve) and eligible (yellow curve) patients

	Ineligible (n = 1004)	Eligible (n = 1532)	P-value
Median age, year (range)	62 (19, 94)	64 (19, 94)	0.080
Female; n (%)	422 (42)	607 (40)	0.238
Stage IV-M1c disease; n (%)	934 (93)	962 (63)	<0.001
ECOG PS; n (%)			
≤1	652 (65)	1532 (100)	
≥2	281 (30)	-	
LDH level; n (%)			<0.001
Normal	528 (54)	1052 (70)	
250-500 U/L	283 (29)	332 (22)	
>500 U/L	167 (17)	124 (8)	
Metastases in ≥3 organ sites; n (%)	620 (62)	549 (36)	<0.001
Brain metastasis; n (%)			
No	308 (31)	1532 (100)	
Yes, asymptomatic	237 (24)	-	
Yes, symptomatic	445 (45)	-	
Liver metastasis; n (%)	311 (32)	387 (25.4)	0.001
Auto-immune disease/IM medication/HIV/AIDS; n (%)	146 (15)	-	
Psychiatric disorder; n (%)	51 (5)	-	
BRAF mutant; n (%)	671 (67)	833 (54)	<0.001

Table 1: patient- and tumor characteristics of ineligible and eligible patients

## Conclusion

Survival of ineligible patients is poorer than survival of eligible patients. However, 22% of the ineligible patients reaches 3-year survival. Survival of ineligible patients mainly depends on LDH, ECOG PS and the presence of brain metastases.

**Our study results can be used for shared-decision making and to set realistic treatment goals for ineligible advanced melanoma patients.**

## More information?

Contact the first author\*:  
[r.ismail@dica.nl](mailto:r.ismail@dica.nl)



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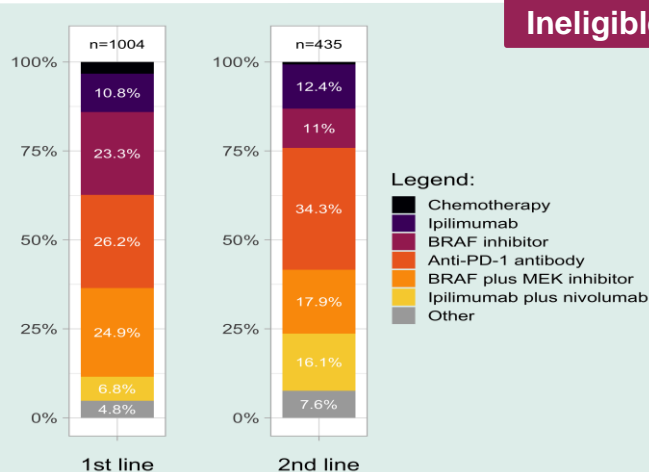


Figure 2: First- and second line systemic treatment of ineligible patients

## Ineligible patients

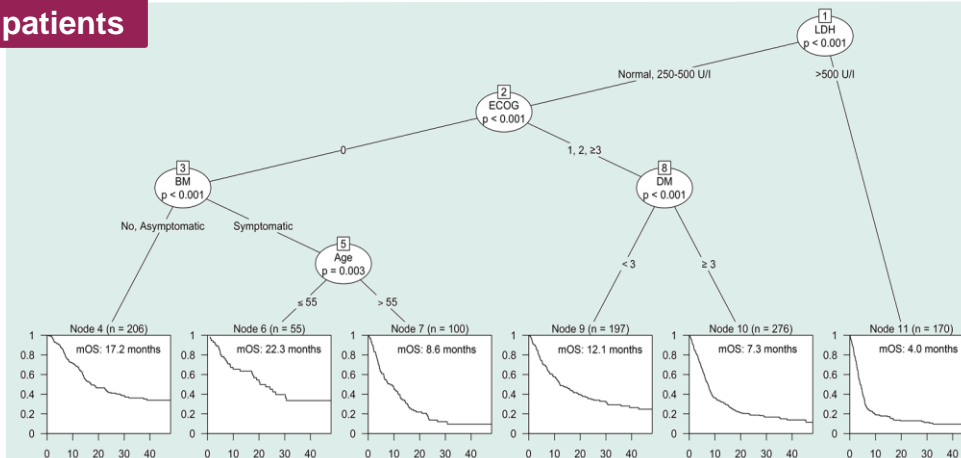


Figure 3: Conditional interference survival tree of all ineligible patients