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Levels of serum EGF concentration as biomarker of response of CIMAvax-EFG vaccine: survival evaluation of advanced NSCLC patients treated in primary health care scenario

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Introduction

Previous studies have shown that basal concentrations of EGF in serum could be considered a biomarker of the efficacy of the therapeutic vaccine CIMAVax-EGF®.
The objective of this study to evaluate the effectiveness of CIMAVax-EGF® for the treatment of advanced NSCLC patients and its relationship with basal serum concentrations of EGF in rea- world setting.

Diagnostic Criteria

Patients with cyto/histological confirmation of non-small Cell lung carcinoma stages IIIB or IV

Key inclusion criteria

1. Signed informed consent for the research.
2. Either sex, 18 years old and older.
3. Histological or cytological confirmation of NSCLC.
4. Ineligible for chemotherapy or radiotherapy or who have received the all oncospecific therapy available in the country and have no other therapeutic option.
5. Performance status classification 0-3 according to ECOG.
6. Life expectancy of 3 months or more.

Endpoints

Primary endpoints
Safety, overall survival according EGF basal serum concentrations.
Secundary endpoints
Survival rates at 12, 18 and 24 months, quality of life.

Conclusions

The results confirm that patients with high EGF serum concentrations and poor prognosis, achieve comparable survival to those with low serum EGF concentrations and a better prognosis of the disease in terms of survival. Patients who received at least 4 doses of treatment, achieved response to first-line onco-specific treatment, and had ECOG between 1 and 2, received the greatest benefit.

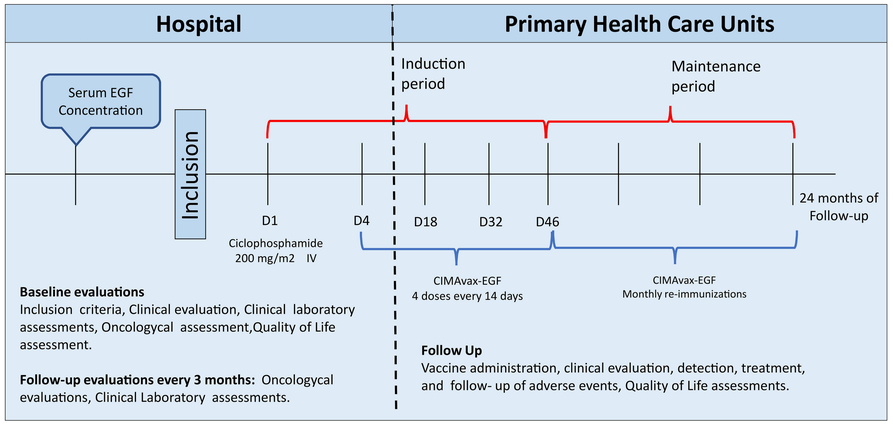


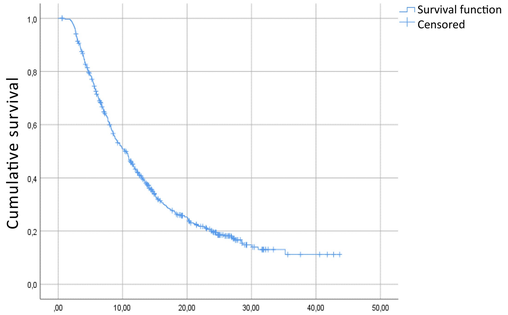
Table 1

Demographic and baseline characteristics of patients.

Characteristics	N = 741	
	No. Patients	%
Age		
<60	188	25.4
=60	553	74.6
Sex		
Female	290	39.1
Male	451	60.9
Smoking history		
Current	241	32.5
Pass	405	54.7
Never	95	12.8
ECOG		
0	305	41.2
1	247	33.3
2	138	18.6
3	51	6.9
Disease stage		
III B	256	34.5
IV	485	65.5

Figure 1

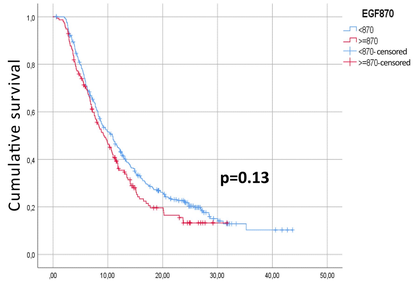
Kaplan-Meier curve in the per-protocol population that received at least 4 doses of CIMAvax-EGF (N=550)



Group	mOS	Survival rates		No.of deaths
		12-months	24- months	
Per protocol group, N= 560	9.6	41.1	18.1	489

Figure 2

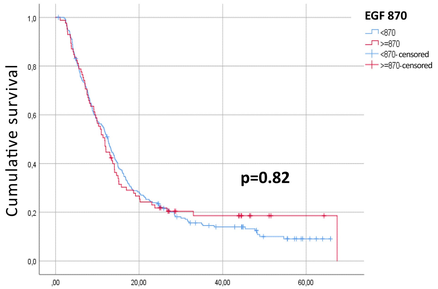
Kaplan-Meier curve in the per-protocol population and basal serum EGF concentrations available (N=489)



Group	mOS	Survivals rates		No. of deaths
		12-months	24- months	
EGF <870 pg/mL, N= 334	10.2	43.6	20.0	298
EGF ≥870 pg/mL, 155	8.9	33.2	13.7	139

Figure 3

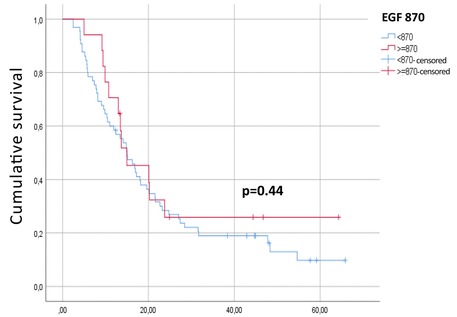
Kaplan-Meier curve of non-progressing patients in the per-protocol population (N=311)



Group	mOS	Survivals rates		No. of deaths
		12-months	24- months	
EGF <870 pg/mL, N= 216	12.6	51.8	23.9	196
EGF ≥870 pg/mL, 76	11.8	47.1	21.8	69

Figure 4

Kaplan-Meier curve of non-progressing patients, in the per-protocol population, ECOG 0-1 (N=82)



Group	mOS	Survivals rates		No. of deaths
		12-months	24- months	
EGF <870 pg/mL, N= 65	15	58.5	28.4	57
EGF ≥870 pg/mL, 17	14.9	70.6	25.9	13

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