

# Pilot cross-over study to evaluate Regenecare topical gel in patients with epidermal growth factor receptor (HER1/EGFR) inhibitors-induced skin toxicity: The final analysis.

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**Abstract:** Background: Papulopustular rash is a dose-limiting toxicity of HER1/EGFR inhibitors. Secondary skin infection can occur from itching. Studies suggested that grade 2 rash might be a surrogate marker for HER1/EGFR inhibitor efficacy; better symptomatic management is desirable to promote optimal use of these agents. Regenecare contains 2% lidocaine for local pain management, marine collagen to promote tissue formation, aloe vera to enhance circulation and promote emollient effect, and sodium alginate to absorb exudates. This study evaluates the effectiveness of Regenecare in relieving the clinical symptoms of HER1/EGFR inhibitors-induced skin rash. Patient tolerability and satisfaction were assessed. Methods: Single center, prospective cross-over study of cancer patients treated with HER1/EGFR inhibitor. At the occurrence of symptomatic skin rash, subjects started applying study gel on the right side of the face and then crossed-over to both sides of the face after 1 week. Weekly facial evaluations with photographs for up to 6 weeks. Tolerability and satisfaction assessed by patient questionnaire. Results: Nineteen patients (M: F = 11:8; Mean age = 54.2 yrs) enrolled with 13 evaluable (9 cetuximab, 3 panitumumab, 1 erlotinib). Repeated Measures Analysis of Variance Model was used. For itch, a significant

improvement over time was noted for the right compared to left side as evidenced by the significant interaction effect. For pain, the interaction effect did not reach statistical significance. All patients tolerated the study gel without any adverse effect and were very satisfied with the outcomes produced by the gel. **Conclusions: Regenecare Gel appears effective in relieving rash-associated itching and pain in patients receiving EGFR inhibitors based on this pilot study.**

	No Treatment		Treatment		Repeated Measures F-test p-value
	Left (Baseline) (n=13)	Left (Week1) (n=13)	Right (Baseline) (n=13)	Right (Week 1) (n=13)	
ITCH					
Mean	1.538	1.577	1.538	0.615	R vs L: p=0.051
SE	0.268	0.225	0.243	0.180	T0 vs T1: p=0.232
					Interaction: p=0.159
SE		0.377	0.345	0.211	
PAIN					
Mean	1.385	1.269	1.308	0.731	R vs L: p=0.004
SE	0.311	0.257	0.308	0.257	T0 vs T1: p=0.126
					Interaction: p=0.006