

RANDOMIZED, OPEN LABEL TRIAL TO COMPARE EFFICACY AND SAFETY OF PEGYLATED INTERFERON ALFA 2A VS ALFA 2B TREATMENT OF PATIENTS WITH CHRONIC HEPATITIS C - 12 WEEKS VIROLOGICAL RESPONSE AMONG PATIENTS WITH GENOTYPE NON 2/3 ANALYSIS

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THERAPEUTICAL EFFICIENCY OF INTERFERON ALFA 2A (PEGASYS, 40 KD) VERSUS INTERFERON ALFA 2B (PEGINTRON, 12 KD) BOTH IN COMBINATION WITH RIBAVIRINE WAS ANALYZED AT 12 WEEK OF TREATMENT.

PATIENTS:

237 CHRONIC HEPATITIS C PATIENTS (PTS) WERE RANDOMIZED INTO TWO GROUPS. THE A GROUP (116 - 49% PTS) WAS TREATED WITH INTERFERON ALFA 2A; THE B GROUP (121- 51% PTS) WITH INTERFERON ALFA 2B. THERE WAS NO STATISTICALLY SIGNIFICANT DIFFERENCE IN MALE / FEMALE RATIOS IN BOTH GROUPS (p > 0,1). GENOTYPING SCORE WAS SIMILAR IN BOTH GROUP (87% VS 92% NON 2 NON 3 GENOTYPE, RESPECTIVELY). THE HIGHEST PERCENTAGE OF PATIENTS IN BOTH GROUPS WAS OF STAGING 1 - 48,2% AND 42,6%, FOLLOWED BY STAGING 2 - 34,5% AND 31,3%, RESPECTIVELY.

CHARACTERISTICS OF GROUP A AND GROUP B

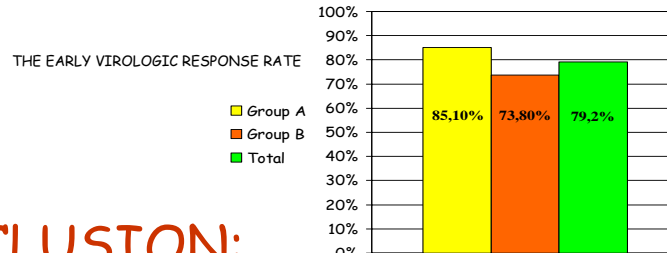
		TOTAL	GROUP A IFN alfa 2a	GROUP B IFN alfa 2b
		237	116 (49%)	121 (51%)
GENDER	MALE	135 (57%)	59 (50,9%)	76 (62,8%)
	FEMALE	102 (43%)	57 (49,1%)	45 (37,2%)
AGE	YEARS	16 - 69	16 - 69	17 - 66
	S D	41,8 ± 11,9	41,5 ± 11,7	42,1 ± 12,2
WEIGHT	Kg	40 - 133	40 - 133	44 - 110
	S D	74,8 ± 15,4	72,8 ± 15,8	76,7 ± 14,8
STAGING	0 - 2	181 (76,4%)	94 (81,0%)	87 (71,9%)
	3 - 4	44 (18,6%)	16 (13,8%)	28 (23,1%)
	NOT PERFORMED	12	6	6
GENOTYPE	2 and 3	25 (10,5%)	15 (12,9%)	10 (8,3%)
	NON 2 or 3	212 (89,5%)	101 (87,1%)	111 (91,7%)

METHODS:

LIVER BIOPSIES WERE ANALYZED ACCORDING TO THE KNODELL'S AND SCHEUER'S SCORES. PATIENTS' AGE AND BODY WEIGHT WERE DETERMINED AND THEIR INFLUENCE ON TREATMENT EFFICIENCY WAS ANALYZED. HCV GENOTYPES WERE DETERMINED WITH VERSANT-LIPA HCV II TEST (INNOGENETICS); HCV RNA WAS DETERMINED WITH HCV RNA ASSAY AND HCV VIRAL LOAD (VL) WITH CA HCV MONITOR TEST (BOTH OF ROCHE DIAGNOSTICS SYSTEM). THE LEVELS OF ALT ACTIVITY WERE DETERMINED WITH ROUTINE TESTS. TREATMENT EFFICIENCY WAS ESTIMATED AT 12 WEEK. EARLY VIROLOGIC RESPONSE (EVR) WAS DEFINED AS DECREASE OF VL > 2 LOG OR UNDETECTABLE HCV RNA.

RESULTS:

DURING THERAPY THREE PTS FROM EACH GROUP WERE EXCLUDED DUE TO SIDE EFFECTS. FOUR OF THEM WERE INFECTED WITH GENOTYPE NON 2/3 AND THEY WERE INCLUDED INTO THE TREATMENT FAILURE GROUP. EFFICIENCY OF THERAPY WAS ANALYZED IN 208 PTS WITH GENOTYPE OTHER THAN 2 OR 3 - 98 PTS IN THE A GROUP AND 110 PTS IN THE B GROUP. THE EVR RATE FOR THE A GROUP WAS 85,1% (86/101) AND 73,8% (82/111) FOR THE B GROUP. THE OVERALL EVR RATE WAS 79,2% (168/212). THE DIFFERENCE IS STATISTICALLY SIGNIFICANT.



CONCLUSION:

EARLY THERAPEUTICAL EFFICIENCY OF INTERFERON ALFA 2A IS SIGNIFICANTLY HIGHER COMPARING TO THIS OBTAINED WITH INTERFERON ALFA 2B.

CHARACTERISTIC OF 12 WEEK NON RESPONDERS

	TOTAL	GROUP A (IFN alfa 2a)	GROUP B (IFN alfa 2b)
	40	12	28
STAGING 3-4	13	3	10
STAGING 1-2	22	6	16
MALE	29	6	23
FEMALE	11	6	5
WEIGHT (kg)	79,2	74,1	81,3
AGE (year)	44,8	46,0	44,3

RISK OF LACK OF EARLY RESPONSE IN 12 WEEK OF TREATMENT - RESULTS OF LOGISTIC REGRESSION ANALYSIS

FACTORS	ODDS RATIO	95% CI
IFN alfa 2a vs IFN alfa 2b (GROUP A vs GROUP B)	0,424	0,198 - 0,907
STAGING 3-4 vs 1-2	1,173	1,018 - 1,352
MALE vs FEMALE	1,837	0,754 - 4,470
WEIGHT (per 1 kg)	1,006	0,978 - 1,034
AGE (per 1 year)	1,023	0,990 - 1,057