

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 PATIENTS (PTS) WITH CHRONIC HEPATITIS C WERE RANDOMIZED INTO TWO GROUPS. THE A GROUP (116 PTS – 49%) WAS TREATED WITH INTERFERON ALFA 2A; THE B GROUP (121 PTS – 51%) 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 OR 3 GENOTYPE, RESPECTIVELY). THE HIGHEST PERCENTAGE OF PATIENTS IN BOTH GROUPS WERE 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
	SD	41,8 ± 11,9	41,5 ± 11,7	42,1 ± 12,2
WEIGHT	Kg	40 - 133	40 - 133	44 - 110
	SD	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 VIRAL LOAD (VL) WITH CA HCV MONITOR TEST (BOTH OF ROCHE DIAGN SYS). THE LEVELS OF ALT ACTIVITY WERE DETERMINED WITH ROUTINE TESTS. TREATMENT EFFICIENCY WAS ESTIMATED AT 12 WEEK. EARLY VIROLOGIC RESPONSE (ERV) WAS DEFINED AS DECREASE OF VL > 2 LOG OR UNDETECTABLE HCV RNA.

RESULTS:

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

CONCLUSION:

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

CHARACTERISTIC OF NON RESPONDERS AFTER 12 WEEKS OF TREATMENT

	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 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