

Randomized phase III GnG study on two schedules of gemtuzumab ozogamicin as adjunct to intensive induction therapy and double-blinded intensive post-remission therapy with or without glasdegib in patients with newly diagnosed acute myeloid leukemia

Authors

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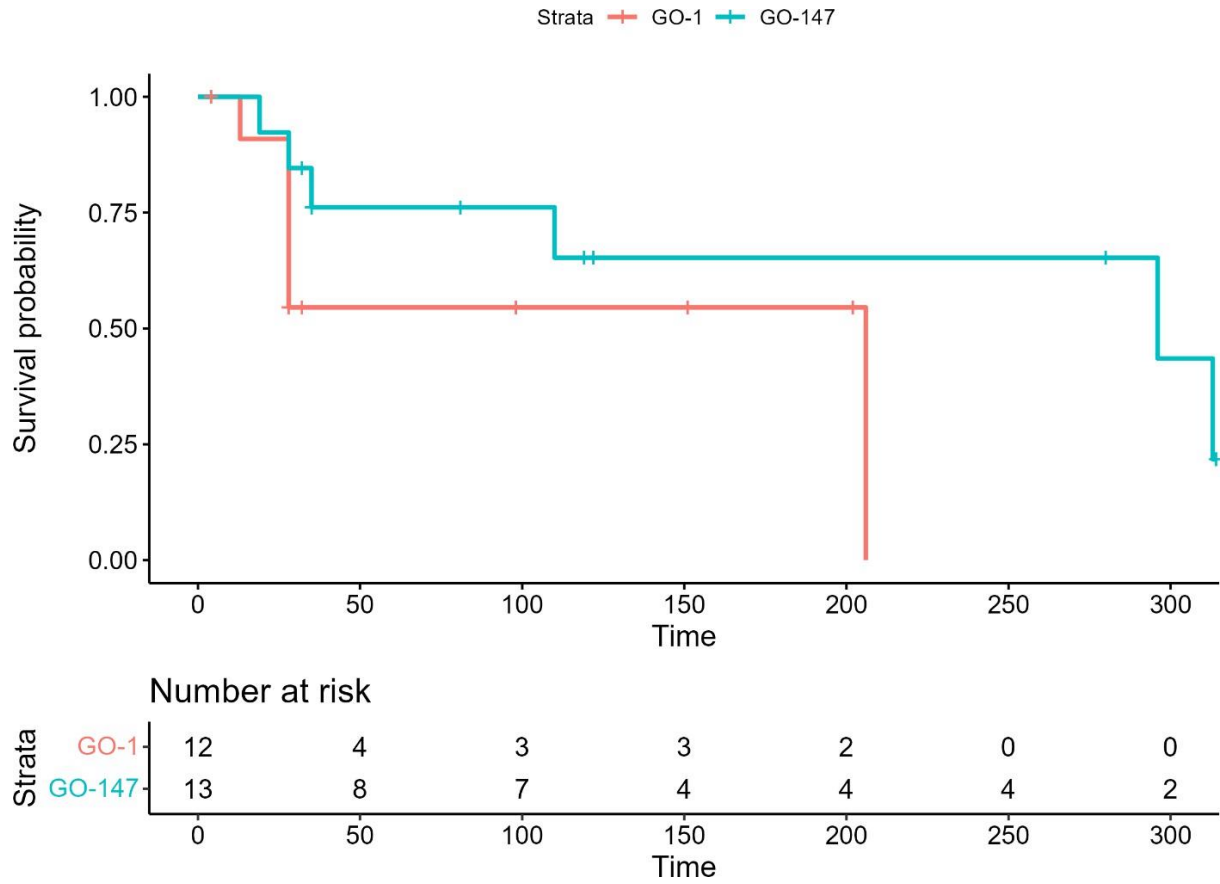
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Supplementary Figure 1: Event-free survival of up-front randomized patients. Blue GO-147 arm, Red GO-1 arm.



Supplementary Figure 2: Relapse-free survival of patients achieving CR/CRi. Blue GO-147 arm, Red GO-1 arm.

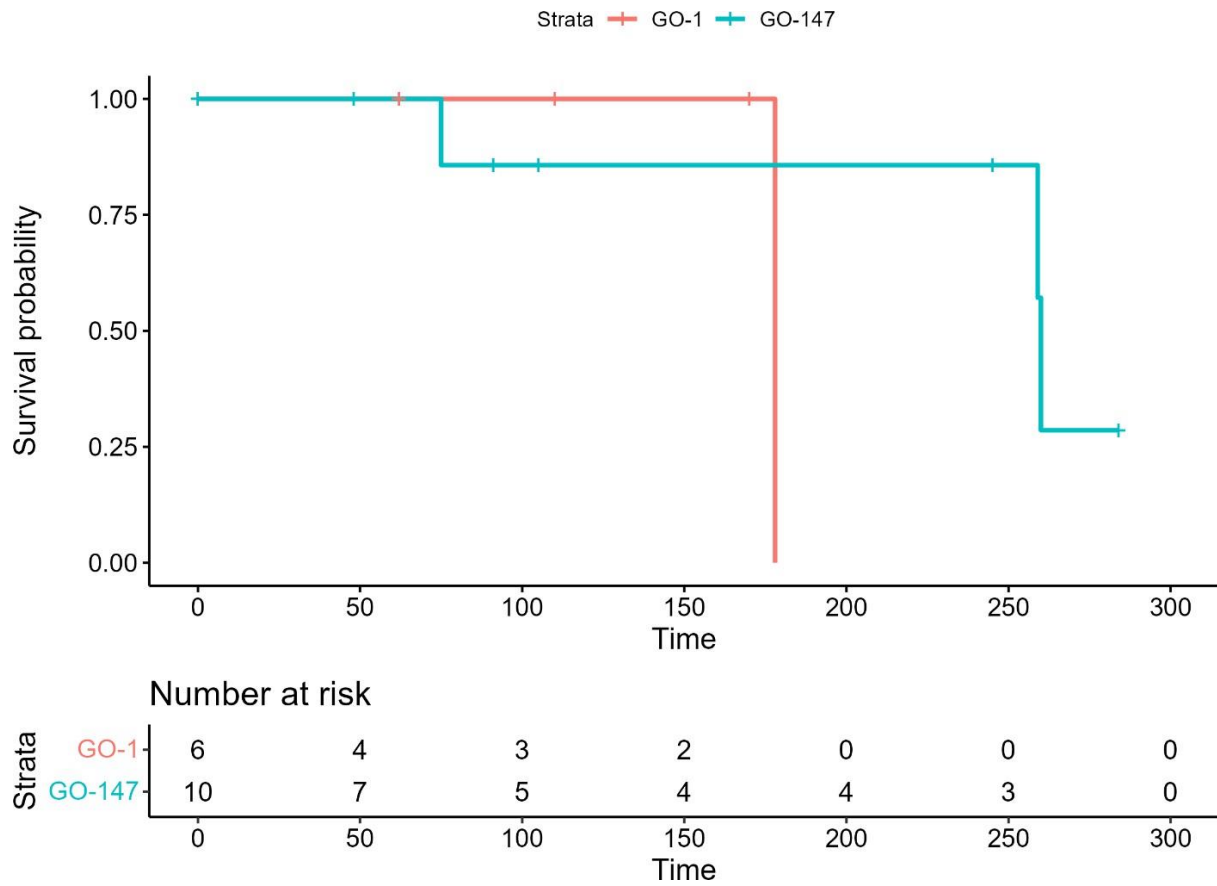


Table S1 Baseline characteristics according to Induction treatment

Table: Baseline Demographics (GO-1 vs. GO-147)

Demographics	GO-1 N=12	GO-147 N=13	Total N=25
Age (N)	12	13	25
- Mean +/- SD	61.1 +/- 7.1	65.2 +/- 5.2	63.2 +/- 6.4
- Median (Q1-Q3)	63.0 (57.0-65.0)	66.0 (62.0-68.0)	64.0 (60.0-68.0)
- Min, Max	46.0, 73.0	57.0, 73.0	46.0, 73.0
Sex			
- male	7 (58.3%)	12 (92.3%)	19 (76.0%)
- female	5 (41.7%)	1 (7.7%)	6 (24.0%)
Ethnic Origin			
- Caucasian/White	12 (100.0%)	13 (100.0%)	25 (100.0%)

Table: Baseline ECOG (GO-1 vs. GO-147)

ECOG	GO-1 N=12	GO-147 N=13	Total N=25
ECOG			
- ECOG 0 - Fully active, able to carry on all pre-disease performance without restriction	5 (41.7%)	7 (53.8%)	12 (48.0%)
- ECOG 1 - Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work	7 (58.3%)	6 (46.2%)	13 (52.0%)

Table: Baseline Cytogenetics (GO-1 vs. GO-147)

Cytogenetics	GO-1 N=12	GO-147 N=13	Total N=25
Type of analysis			
- R-banding analysis	1 (10.0%)	1 (10.0%)	2 (10.0%)
- G-banding analysis	9 (90.0%)	9 (90.0%)	18 (90.0%)
- missing	2	3	5
Karyotype			
- normal	9 (75.0%)	7 (53.8%)	16 (64.0%)
- aberrant	3 (25.0%)	6 (46.2%)	9 (36.0%)

Table: Baseline Extended Blood Chemistry (GO-1 vs. GO-147)

Extended blood chemistry	GO-1 N=12	GO-147 N=13	Total N=25
Result LDH (N)	10	13	23
- Mean +/- SD	321.0 +/- 155.0	392.4 +/- 263.5	361.4 +/- 221.4
- Median (Q1-Q3)	296.9 (203.0-370.0)	283.0 (238.0-401.0)	286.8 (225.0-401.0)
- Min, Max	152.0, 683.0	132.0, 986.0	132.0, 986.0
- Missing	2	0	2

Table: Baseline Hematology (GO-1 vs. GO-147)

Hematology	GO-1 N=12	GO-147 N=13	Total N=25
Result Hemoglobin (N)	12	13	25
- Mean +/- SD	8.5 +/- 1.4	9.5 +/- 3.4	9.0 +/- 2.6
- Median (Q1-Q3)	8.4 (7.8-9.5)	9.3 (7.6-11.6)	8.7 (7.7-10.8)
- Min, Max	5.5, 10.8	3.8, 16.9	3.8, 16.9
Result Hematocrit (N)	12	13	25
- Mean +/- SD	25.4 +/- 3.2	27.0 +/- 6.7	26.2 +/- 5.3
- Median (Q1-Q3)	25.8 (23.5-28.0)	28.3 (22.3-32.2)	26.2 (23.0-30.0)
- Min, Max	19.0, 30.0	15.9, 34.6	15.9, 34.6
Result Platelet count (N)	12	13	25
- Mean +/- SD	109.7 +/- 76.9	76.5 +/- 76.2	92.4 +/- 76.8
- Median (Q1-Q3)	99.0 (75.0-107.0)	41.0 (33.0-88.0)	88.0 (34.0-99.0)
- Min, Max	21.0, 292.0	23.0, 295.0	21.0, 295.0
Result Neutrophils (N)	7	12	19
- Mean +/- SD	3.1 +/- 4.4	1.6 +/- 2.4	2.1 +/- 3.2
- Median (Q1-Q3)	0.9 (0.5-6.7)	0.7 (0.4-1.5)	0.9 (0.5-2.0)
- Min, Max	0.1, 11.6	0.0, 8.5	0.0, 11.6
- Missing	5	1	6
Result Blasts (N)	9	11	20
- Mean +/- SD	26.1 +/- 24.3	33.7 +/- 35.5	30.3 +/- 30.4
- Median (Q1-Q3)	16.0 (9.0-33.0)	26.0 (1.0-68.7)	21.0 (4.5-55.5)
- Min, Max	0.0, 70.0	0.0, 89.0	0.0, 89.0
- Missing	3	2	5

Table: Baseline Diagnosis of AML (GO-1 vs. GO-147)

Diagnosis of AML	GO-1 N=12	GO-147 N=13	Total N=25
WHO-Classification of AML			
- AML with recurrent genetic abnormalities	4 (36.4%)	4 (30.8%)	8 (33.3%)
- AML with myelodysplasia-related changes	2 (18.2%)	1 (7.7%)	3 (12.5%)
- Therapy-related myeloid neoplasms	0 (0.0%)	1 (7.7%)	1 (4.2%)
- AML not otherwise specified (NOS)	5 (45.5%)	7 (53.8%)	12 (50.0%)
- missing	1	0	1
Subtype for AML with Recurrent genetic abnormalities			
- AML with t(8;21)(q22;q22.1); RUNX1- RUNX1T1	1 (25.0%)	0 (0.0%)	1 (12.5%)
- AML with t(9;11)(p22;q23); MLLT3-KMT2A	0 (0.0%)	1 (25.0%)	1 (12.5%)
- AML with mutated NPM1	2 (50.0%)	3 (75.0%)	5 (62.5%)
- AML with biallelic mutations of CEBPA	1 (25.0%)	0 (0.0%)	1 (12.5%)
- missing	8	9	17

Subtype for AML with myelodysplasia-related changes			
- defined by cytogenetics	2 (100.0%)	1 (100.0%)	3 (100.0%)
- missing	10	12	22
Disease for therapy-related myeloid neoplasms			
- Cancer	0 (0.0%)	1 (100.0%)	1 (100.0%)
- missing	12	12	24
Chemotherapy for therapy-related myeloid neoplasms			
- yes	0 (0.0%)	1 (100.0%)	1 (100.0%)
- missing	12	12	24
Radiotherapy for therapy-related myeloid neoplasms			
- yes	0 (0.0%)	1 (100.0%)	1 (100.0%)
- missing	12	12	24
Subtype for AML not otherwise specified (NOS)			
- AML with minimal differentiation (FAB M0)	1 (20.0%)	1 (14.3%)	2 (16.7%)
- AML without maturation (FAB M1)	0 (0.0%)	3 (42.9%)	3 (25.0%)
- AML with maturation (FAB M2)	2 (40.0%)	3 (42.9%)	5 (41.7%)
- Acute myelomonocytic leukemia (FAB M4)	2 (40.0%)	0 (0.0%)	2 (16.7%)
- missing	7	6	13