Hypo-/normal cellular high-risk MDS/AML, case report form.

Investigator:	
Hospital:	
City:	
Patient initials:	
Date of birth, personal number:	D: _ _ M: _ _ _ Y: _ _ _ _ Pers. no: _ _ _ _ _ *(Please write the first three letters of the month (e.g.: JAN))*
Sex:	Male Female
Date of diagnosis:	D: _ _ M: _ _ _ Y: _ _ _ _
Date of death:	D: _ _ M: _ _ _ Y: _ _ _ _
Primary cause of death:	
Secondary cause of death:	
Signed informed consent for patients alive, date:	D: _ _ M: _ _ _ Y: _ _ _ _
Subject number:	*(to be filled out by the study centre)* No:
Date of subject number:	D: _ _ M: _ _ _ Y: _ _ _ _
Report received:	D: _ _ M: _ _ _ Y: _ _ _ _
Signature of study centre member:	

For registration please send the CRF to study centre:

Ingunn Dybedal, Avdeling for Blodsykdommer, OUS – Rikshospitalet, Postboks 4950 Nydalen, 0424 Oslo

Inclusion criteria:

1. ≥ 18 years of age at the time of signing the informed consent form Yes _ No _
2. Low/normal cellular high-risk MDS or low/normal cellular AML Yes _ No _
3. Subject has signed the informed consent form or is not alive at time of inclusion Yes _ No _

If any answer is *no*, the subject is not eligible for the trial.

Exclusion criteria:

1. Subject alive has <u>not</u> signed the informed consent Yes _ No _
2. High cellularity in the bone marrow biopsy Yes _ No _
3. Two or more cytogenetic aberrations or chromosome 7 aberrations. Yes _ No _

If any answer is *yes*, the subject is not eligible for the trial.

Investigator's signature: _____ D: _ _ M: _ _ _ Y: _ _ _ _

Diagnosis	
Reason of consulting a hematologist	
Date of MDS /AML diagnosis	D: _ _ M: _ _ _ Y: _ _ _ _
Type of **MDS** at debut, WHO-classification:	
Prognostic score, IPSS-R:	
Type of **MDS** when starting melphalan treatment, WHO classification:	
Prognostic score, IPSS-R:	
Type of **AML** at debut, WHO-classification:	
Secondary AML? Please specify:	
Type of **AML** when starting melphalan treatment, WHO-classification:	

ECOG status

ECOG Performance Status

Developed by the Eastern Cooperative Oncology Group, Robert L. Comis, MD, Group Chair.*

GRADE	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
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
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

*Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol.* 1982;5:649-655.

At melphalan treatment cycle	Treatment start, date	ECOG status
1	D: _ _ M: _ _ _ Y: _ _ _ _	
2	D: _ _ M: _ _ _ Y: _ _ _ _	
3	D: _ _ M: _ _ _ Y: _ _ _ _	
4	D: _ _ M: _ _ _ Y: _ _ _ _	

Has the subject relevant medical/surgical history or concurrent disease:

Year:	Diagnosis:	Past: Y/N	Current: Y/N

Systemic therapy at time of MDS/AML diagnosis: Y / N.

If systemic therapy, please fill out:

No	*Drug name*	*Dose*	*Unit*	*Freq*	*Route*	*Indication*	*Start date DD-MON-YYYY*	*Ongoing*	*Stop date DD-MON-YYYY*
1									
2									
3									
4									
5									
6									
7									
8									
9									

Systemic therapy at time of MDS/AML diagnosis:

No	*Drug name*	*Dose*	*Unit*	*Freq*	*Route*	*Indication*	*Start date DD-MON-YYYY*	*Ongoing Yes/No*	*Stop date DD-MON-YYYY*
10									
11									
12									
13									
14									
15									
16									
17									

Prior stem cell transplantation: Y / N. If yes, please specify:

Allogenic: D: _ _M: _ _ _Y: _ _ _ _ Date of procedure

Autologous: D: _ _M: _ _ _Y: _ _ _ _ Date of procedure

Bone marrow results:

Date of specimen	**Bone marrow biopsy**	
	Cellularity %	*Blasts (CD34+) %*
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		

Date of specimen	**Karyotype description and/or FISH**	*Date of specimen*	**Molecular pathology**
D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _	
D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _	
D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _	
D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _	

Lab. values:

		Date D: _ _ M: _ _ _ Y: _ _ _ _	**Hb**	**Lkc**	**Neut**	**Plt**	**LD**	**Beta-2-mikro**
Cycle no								
0	**First consultation**	_ _ ._ _ _. _ _ _ _						
1	**Melphalan cycle no. 1, start**	_ _ ._ _ _. _ _ _ _						
	Cycle no. 1, best response	_ _ ._ _ _. _ _ _ _						
	Melphalan cycle no. 1, finished	_ _ ._ _ _. _ _ _ _						
	Duration of response #	_ _ ._ _ _. _ _ _ _						
2	**Melphalan cycle no. 2, start**	_ _ ._ _ _. _ _ _ _						
	Cycle no. 2, best response	_ _ ._ _ _. _ _ _ _						
	Melphalan cycle no. 2, finished	_ _ ._ _ _. _ _ _ _						
	Duration of response #	_ _ ._ _ _. _ _ _ _						
3	**Melphalan cycle no. 3, start**	_ _ ._ _ _. _ _ _ _						
	Cycle no 3, best response	_ _ ._ _ _. _ _ _ _						
	Melphalan cycle no. 3, finished	_ _ ._ _ _. _ _ _ _						
	Duration of response #	_ _ ._ _ _. _ _ _ _						

Duration of response: Significantly improved peripheral blood values compared with pre-treatment values.

MDS/AML related treatment before melphalan was started:

No	Treatment, type	Freq, day/week	Start, date	Stop, date	Treatment period (weeks)
1			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
2			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
3			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
4			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	

Melphalan treatment:

Cycle no	Doses	Treatment start, date	Treatment finished, date	Treatment period (weeks)
1		D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
		D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
		D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
		D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
		D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
		D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
		D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	

Treatment after melphalan was finished:

No	Treatment, type	Freq, day/week	Start, date	Stop, date	Treatment period (weeks)
1			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
2			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
3			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
4			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	
5			D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _	

Transfusions the last 8 weeks before Melphalan treatment cycle no. 1 was started:

Numbers of SAG units:	
Numbers of thrombocyte units:	

Transfusions after Melphalan treatment cycle no. 1 was started:

Date:	**SAG units:**	**Trc units:**
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
Total:		

Date:	**SAG units:**	**Trc units:**
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
D: _ _ M: _ _ _ Y: _ _ _ _		
Total:		

Hospitalization:

No:	Admission, date:	Discharge, date:
1	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
2	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
3	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
4	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
5	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
6	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
7	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
8	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
9	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
10	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
11	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
12	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
13	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
14	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
15	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _
16	D: _ _ M: _ _ _ Y: _ _ _ _	D: _ _ M: _ _ _ Y: _ _ _ _