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EORTC Lymphoma group - GELA

H 10

RANDOMIZATION CHECKLIST

INSTRUCTIONS: *Eligible patients should be randomized via INTERNET (http://www.eortc.be/random) or by telephoning the EORTC Data Center (+32 2 774 1600) Monday to Friday from 9am to 5pm, with the exception of official Belgian bank holidays. Please consult the web-site for yearly updated information (http://www.eortc.be). Please complete this form before randomization and send it immediately following randomization with the other baseline forms to:EORTC DATA CENTER (Lymphoma Data Manager) ♦ Avenue E. Mounier, 83, BP 11 ♦ 1200 - Brussels ♦ Belgium*

EORTC SEQUENTIAL IDENT.NO (GIVEN AT REGISTRATION) | PATIENT CODE (CAPITAL LETTERS) | DATE OF BIRTH (*D D M M Y Y Y Y*) | PATIENT HOSPITAL CHART NUMBER

INSTITUTION : ..... INST. N°: | RESPONSIBLE PHYSICIAN : .....

Histological documented Hodgkin's lymphoma (HL): 01

1 = Nodular Lymphocyte Predominant
2 = Nodular Sclerosis
3 = Mixed Cellularity
4 = Lymphocyte Depletion
5 = Lymphocyte Rich Classical
6 = UnClassifiable
8 = other, specify: 02

Ann Arbor clinical stage: 1=I, 2=II, 3=III, 4=IV 03

Supradiaphragmatic disease: 0 = no, 1 = yes 04

Prognostic factors for treatment group F – U:

Number of nodal areas 05

B symptoms: 0 = no, 1 = yes 06

ESR ..... mm/h 07

MT ratio 08

Treatment group according to investigator: 1 = favourable, 2 = unfavourable 09

According to the data provided the risk group will be calculated during the randomization, if you want to verify some data go back and confirm the risk group!

Prior therapy for Hodgkin's lymphoma: 0 = no, 1 = yes 10

Baseline FDG-PET scan performed and available before entry into the trial: 0 = no, 1 = yes 11

If yes, please provide the date (dd/mm/yyyy) 12

Date of prospectively planned FDG-PET scan after 2 cycles of ABVD (dd/mm/yyyy) 13

FDG-PET scan adress: 14

Name resp. nuclear med physician: 15

Tel and e-mail contact person: 16

WHO performance status (0-4) 17

Sex: 1 = male, 2 = female 18

Is the patient of child-bearing/reproduction potential: 0 = no, 1 = yes 19

If this patient is a **woman**, is she pregnant or lactating: 0 = no, 1 = yes 20

For all patients, has she / he agreed to use adequate contraceptive method throughout the study and for up to 6 months following discontinuation of study drug: 0 = no, 1 = yes 21

Severe cardiac, pulmonary, neurologic, psychiatric or metabolic disease : 0 = no, 1 = yes 22

Unstable diabetes mellitus: 0 = no, 1 = yes 23

Please complete & attach all pages up to page 2 of this form

(20051) Date: __/__/____ **Investigator's signature :** .....

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		ULN		Actual value	
Serum creatinine	µmol/l		24	.....	28
	or mg/dl	.	25	..... .	29
Total bilirubin	µmol/l		26	.....	30
	or mg/dl	.	27	..... .	31

Any concomitant or previous malignancies *(with the exception of basal cell skin tumors, adequately treated carcinoma in situ of the cervix and a cancer that has been in complete remission for > 5 years)*: 0 = no, 1 = yes 32

Known HIV infection: 0 = no, 1 = yes 33

Do all conditions (psychological, familial, sociological and geographical) permit medical follow-up: 0 = no, 1 = yes 34

Date of signature of written informed consent according to ICH/GCP and/or applicable national laws (dd/mm/yyyy) 35

Planned date of treatment start (dd/mm/yyyy) 36

Where will the Chemotherapy be given: 0 = in my institution, 1 = in a satellite institution 37

If satellite institution, specify: .....] 38

Where will the Radiotherapy be given: 0 = in my institution, 1 = in a satellite institution 39

If satellite institution, specify: .....] 40

NOW CONNECT TO THE INTERNET (http:// www.eortc.be/random)
OR CALL THE DATA CENTER (+32/2/774 16 00)

INFORMATION GIVEN BY THE DATA CENTER

Patient sequential number *(seqid)* 41

Date of randomization (dd/mm/yyyy) 42

Treatment allocated: 43

FAVOURABLE group (F)	**UNFAVOURABLE group (U)**
1 = ABVD x 2 then FDG-PET evaluation: negative PET: ABVD x 1 + IN-RT positive PET: ABVD x 1+ IN-RT	3 = ABVD x 2 then FDG-PET evaluation: negative PET: ABVD x 2 + IN-RT positive PET: ABVD x 2 + IN-RT
2 = ABVD x 2 then FDG-PET evaluation: negative PET: ABVD x 2 positive PET: escalated BEACOPP x 2 + IN-RT	4 = ABVD x 2 then FDG-PET evaluation: negative PET: ABVD x 4 positive PET: escalated BEACOPP x 2 + IN-RT

Please send this randomization form together with the on-study form !

(20051) Date: __/__/____ **Investigator's signature :** .....