TOTEM Study

Clin. Trial identifier: NCT00916708

MaNGO_MITO

Gynecologic Cancer InterGroup

GCIG May 30 & 31, 2013, Chicago

Appropriateness evaluation of follow up procedures in Gynaecology Oncology

TOTEM Study: Multicentric randomized controlled clinical trial between two follow up regimens with different tests intensity in endometrial cancer treated patients.

Italian Group about Gynaecology Oncology Follow Up

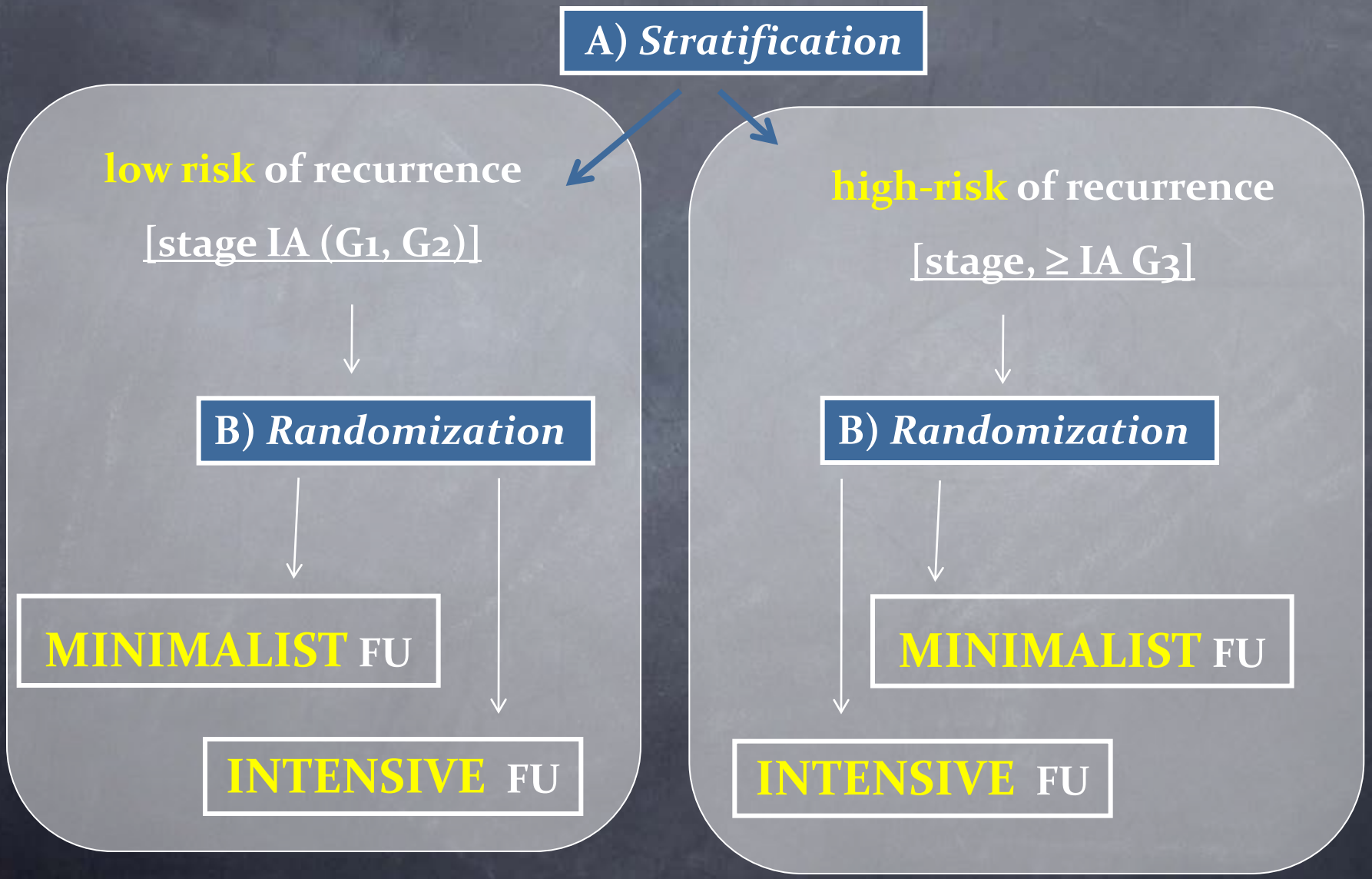
Inclusion criteria

- patients treated surgically for endometrial cancer, if in complete clinical remission confirmed by imaging stage FIGO I-IV
- not previous or concurrent neoplasia (with the exception of carcinoma in situ of the cervix and basalioma of the skin)
- other contemporaneous RCT may be allowed if there is not any restriction concerning follow up
- obtaining a written informed consensus before randomization
- age > 18 years

Exclusion criteria

- presence of any psychological, familial, sociological or geographical condition that could potentially limit the compliance to the protocol and the follow-up planned: all these situations must be discussed with the patient before the randomization
- previous, concurrent or second malignancies
- endometrial carcinoma in the context of a hereditary syndrome
- conditions which contraidicate medical tests scheduled according to follow-up regimen

Study design



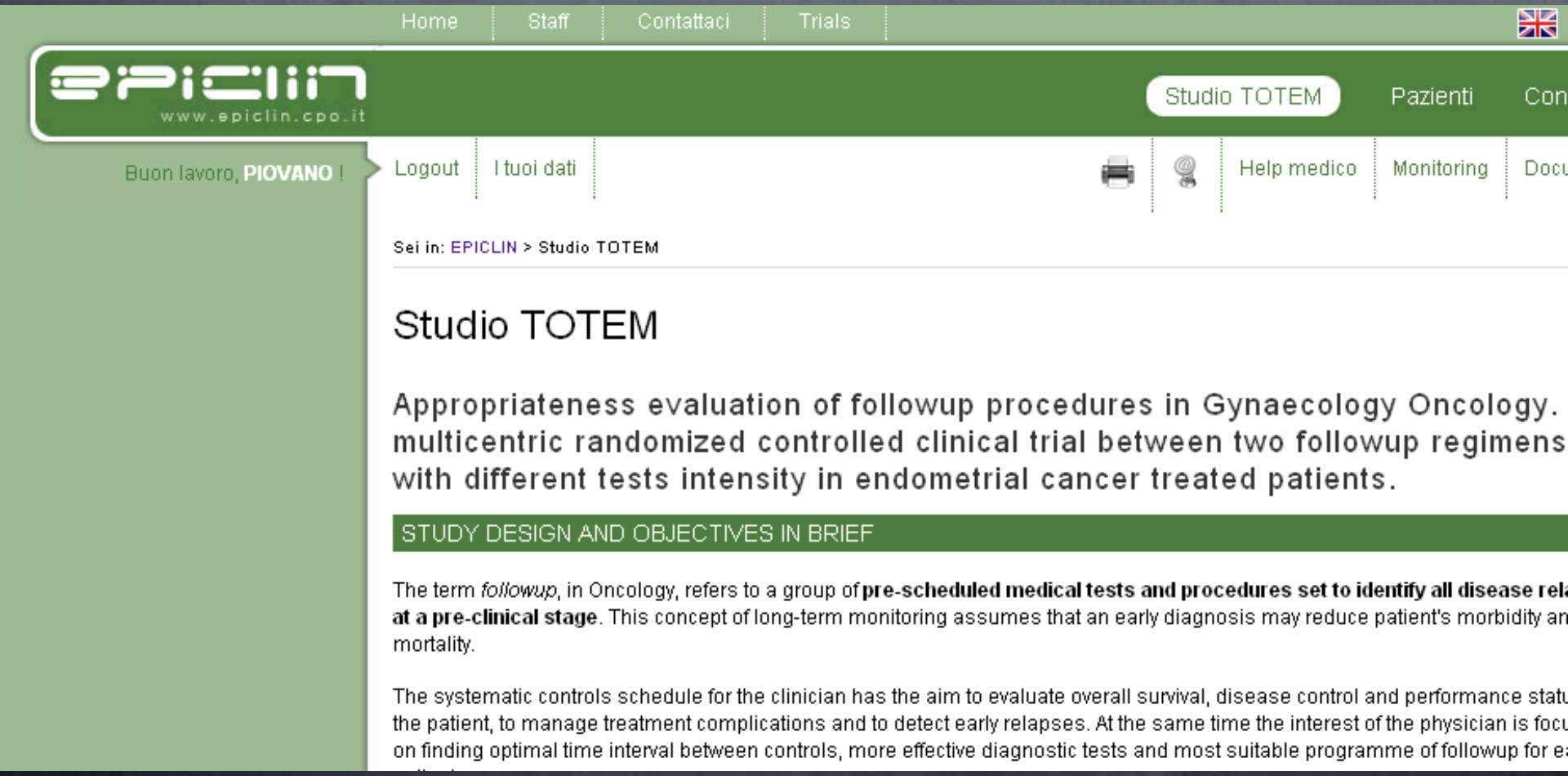
Primary Objective

Compare the effect of the two follow-up regimens on the (5-y) overall survival.

Secondary Objectives

- Quantify the intensive program possibility to advance the diagnosis of recurrence comparing to minimalist program
- Assessing the accuracy of the two schemes of follow-up as the ability to diagnose the relapse in asymptomatic patients
- Describe the compliance to different follow-up programs
- Formally evaluate quality of life and patients satisfaction about the two strategies of follow-up
- Formally evaluate the cost-effectiveness and the cost-utility of the two regimens

Randomization → website **www.epiclin.it**



LOW RISK

LOW RISK Arm 1	0	4	6	8	12	16	18	20	24	30	36	42	48	54	60
Visit	X		X		X		X		X	X	X	X	X	X	X
QoL Questionnaire	X	X			X				X		X		X		X

LOW RISK Arm 2	0	4	6	8	12	16	18	20	24	30	36	42	48	54	60
Visit	X	X		X	X	X		X	X	X	X	X	X	X	X
Pap Smear					X				X		X		X		X
CT chest, abdomen, pelvis					X				X						
QoL Questionnaire	X	X			X				X		X		X		X

HIGH RISK

HIGH RISK Arm 1	0	4	6	8	12	16	18	20	24	30	36	42	48	54	60
Visit	X	X		X	X	X		X	X	X	X	X	X	X	X
CT chest, abdomen, pelvis					X				X						
QoL Questionnaire	X	X			X				X		X		X		X

HIGH RISK

HIGH RISK Arm 2	0	4	6	8	12	16	20	24	28	32	36	42	48	54	60
Visit	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Ca125		X		X	X	X	X	X	X	X	X	X	X	X	X
Abdomen & TV US		X		X		X	X		X	X		X		X	
Pap Smear					X			X			X		X		X
CT chest, abdomen, pelvis					X			X			X		X		X
QoL Questionnaire	X	X			X			X			X		X		X

Planned analysis

Low risk patients show a 5-year survival rate of 0.85
High risk patients show a 5-yearssurvival rate of 0.65

The study has been planned in order to see if one of the two follow-up regimens may increase 5 year overall survival from 0.75 to 0.80

beta = 0.20 and alpha error (two tails) = 0.05

Assuming a rate of drop-out about 5% it it will be

necessary to enrol in the study about 2300 patients

(1150 in each arm)

an interim analysis will be conduced when about 30-35% of expected events have been reported

Update 05/13

✓36 Institutions across Italy joined the study and are enrolling patients

✓ 876 patients enrolled on 21st May 2013 (+ 238*)

Median follow up: 15 months

* Compared to 1st June 2013

Quality of data

876 patients enrolled
825 patients randomized
(51 patients with ongoing adjuvant treatment)

288 (33%) patients with all filled form

521 (59%) patients with 1 or more forms to be filled

146 (17%) patients with any filled form

if you want to share TOTEM trial ..

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LR: low risk m: minimalist
HR: high risk I: Intensive

	Relapses	Deaths	Withdrawals*
LR m	4	1	18
LR I	2		14
HR m	13	1	28
HR I	10	3	22
TOT	29	5	82

3.3 % **0.6 %**

* Relapse, Withdrawal of informed consensus, Bad compliance, Lost during the Study, Death, New neoplasia

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