

	Institutional Review Board	Final Report	AF 17-01/5.0
	Faculty of Medicine, Chulalongkorn University		Page 1/2

Protocol title (ไทย) การตรวจระดับ CA 125 และ HE4 ก่อนผ่าตัดเพื่อประเมินปัจจัยเสี่ยงในผู้ป่วยมะเร็งเยื่อบุโพรงมดลูกระยะที่หนึ่งท วงคลินิก (English) Preoperative CA 125 and HE4 level for the prediction of high risk factors in clinical stage 1 endometrial cancer patients	IRB NO. <u>477/6</u> <u>0</u>
Study Code :	
Principal Investigator: แพทย์หญิงธาริณี แมนชนะ	
Phone number : 087-7161199	E-mail address: T_manchana@hotmail.com
Sponsor's Name :	
Address :	
Phone number :	E-mail address :
Study site(s): โรงพยาบาลจุฬาลงกรณ์	
Objective(s) :	
To evaluate the cut-off value of preoperative serum CA125 and HE4 level for prediction of high risk factors in endometrial cancer patients.	
Study material(s) :	
Study dose(s) :	
Treatment form :	
Duration of the study: 1 July 2017-30 November 2018	
Total number of study participants: 102	No. of Study Arms :1
Number of participants recruited in the study: 102	
Number of dropout participants in the study: 0	
Number of SAE/SUSARs occurred: 0	
Number of Non-Compliance / Protocol violation occurred: 0	
Post trial access to study drug:	
Brief summary of the result:	
CA125 and HE4 level significantly elevated in the patients with deep myometrial invasion ($\geq 50\%$), stage 2+, lymphovascular space invasion (LVSI). According to the ROC curve, the optimal cut-off value for CA125 and HE4 for prediction of having deep myometrial invasion, stage 2+, LVSI, and node metastasis were 24 U/ml and	

110 pmol/L, respectively. CA125 and HE4 level had similar sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for prediction of deep myometrial invasion, LVSI, stage2+, and node metastasis. Combination of CA125 and HE4 does not increase prediction rate of high risk factors.

Investigator's signature
date.....17...../.....Dec...../.....2018.....
(Please retain a copy of the completed form for your record keeping.)

Reviewer's comments :

Reviewer's signature **date**...../...../.....
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