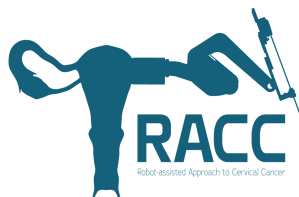


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## SHAPE and RACC

Dear all investigators!

As you probably all know, the results from the international phase-III trial SHAPE were presented at ASCO earlier in June. In the SHAPE trial, 700 women with stage 1A2 or 1B1 ( $\leq 2$ cm) were randomized to radical or simple hysterectomy. No difference for the primary endpoint (pelvic recurrence rate) was observed between the arms with 11 and 10 events after simple and radical hysterectomy respectively. Fewer surgical complications and better quality of life were observed with simple hysterectomy.

The Trial Steering Committee for the RACC-trial has discussed the results from the SHAPE-trial and concludes the following:

- 1. We need to await the final publication to understand the full implications of the SHAPE-trial. Moreover, we need to understand if any protocol changes have been made regarding the power analysis since the presented results only comprise 21 events for the primary endpoint.*
- 2. The results from the SHAPE-trial will most definitely have a significant impact on national and international guidelines. However, at this point, no guidelines have been changed.*
- 3. The TSC for the RACC-trial has therefore concluded that inclusion and exclusion criteria will remain unchanged for the time being. We expect this to change once the SHAPE-trial has been published. Don't hesitate to contact us if you have questions concerning enrollment in the trial.**

**We wish all investigators a fabulous summer,  
look out for the next Newsletter as we will  
announce the 600th enrolled patient within a few  
days!**

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