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# COMBINING URINARY LUTEINIZING HORMONE (LH) TESTING WITH ULTRASOUND MONITORING FOR TIMING INTRAUTERINE INSEMINATION CYCLES: A RANDOMIZED CONTROLLED TRIAL



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## OBJECTIVE

To determine if using urinary LH testing (u-LH) in conjunction with ultrasound (US) monitoring increases pregnancy rates (PR) in intrauterine insemination (IUI) cycles when compared to US monitoring alone.

## DESIGN

Prospective randomized controlled trial of women undergoing IUI cycles at a university-affiliated private infertility clinic between January 2011 and March 2016 (Trial registration number NCT01205555).

## MATERIAL AND METHODS

Women aged less than 40 years and undergoing IUI for the following indications: unexplained infertility, mild male factor and donor sperm insemination, were included. Only women with an antral follicle count  $\geq 10$ , basal FSH  $< 10$  IU/L, and at least one patent tube were eligible to participate in the study. We included IUI performed in a natural cycle or following ovarian stimulation with clomiphene citrate or letrozole. Patients with polycystic ovarian syndrome or other causes of oligo-anovulation, patients taking other fertility drugs, and cycles with a total motile sperm count  $< 5$  million/ml were excluded from the study. On the day of the first US, patients were randomized by a computer generated random number table to the control or study group. Patients in the control group had standard US monitoring, with hCG administered when the leading follicle reached 18 mm and IUI performed 36 hours later. Patients in the study group were instructed to start u-LH testing, twice daily, when the leading follicle reached 14 mm, and continue until the time of hCG administration or a positive u-LH; IUI was performed 36 hours after hCG administration or the day after a positive u-LH, whichever occurred first. Our primary outcome was PR (positive pregnancy test) and our secondary outcome was the rate of positive u-LH before hCG.

## SUPPORT

The study was funded by clinique ovo.

## RESULTS

336 cycles were initially included, and 42 cycles were excluded for protocol violation. In total, 294 cycles were randomized to the study (n=144) or control group (n=150). Patients' characteristics were comparable in the two groups. There was no difference in the PR between the study and the control group (17.4% (25/144) vs 17.3% (26/150), p=0.99, respectively). In the study group, the rate of positive LH testing before hCG was 11.8% (17/144), and there was no difference in the PR between patients who had the IUI after a positive u-LH and those who had an hCG injection (11.8% (2/17) vs 18.1% (23/127), p=0.33, respectively). A multivariate logistic regression analysis failed to identify any significant predictors of a positive u-LH prior to hCG administration.

	US+u-LH (n = 144)	US (n = 150)	p value
Pregnancy rate	17.4% (25/144)	17.3% (26/150)	p = 0.99

X<sup>2</sup> tests were used to assess for differences between groups.

US+u-LH group (n = 144)			
	IUI after positive LH test (n = 17)	IUI after hCG injection (n = 127)	p value
Pregnancy rate	11.8% (2/17)	18.1% (23/127)	p = 0.33

X<sup>2</sup> tests were used to assess for differences between groups.

## CONCLUSIONS

Combining urinary LH testing with ultrasound monitoring does not improve pregnancy rates compared with US monitoring alone. However, an endogenous LH surge occurs in 11.8% of IUI cycles before hCG administration when monitoring is based on US alone.