

# Discover How SGF's Award-Winning Research Is Helping Patients Conceive with Less Medication

The volume of patients we care for gives our practice tremendous insight into the best treatment protocols, and we are committed to giving back to our field by finding better, safer, more efficient ways to take the very best care of our patients. Our team of physician scientists collaborate with researchers from across the nation, including fellows from the National Institute of Health, to analyze, author, and present findings aimed at improving patient outcomes.

At this year's American Society for Reproductive Medicine Scientific Congress & Expo, Shady Grove Fertility made a significant contribution with eight oral and three poster presentations. Two of the studies presented took home noteworthy distinctions. Our study that evaluated alternatives to daily IM progesterone injections during a frozen embryo IVF cycle offered such clinical significance, it took home top prize. The study SGF presented about how African-American women fair during infertility treatment sheds important light for primary care physicians, OB/GYNs, and fertility specialists alike, and was also a prize-worthy contribution.

## TOP FINDINGS

**Scientific Congress Prize Paper Award:** SGF research shows patients **achieve equivalent live birth rates** during a frozen embryo cycle with **fewer intramuscular progesterone injections** when combined with vaginal suppositories.

**Health Disparities Special Interest Group Prize:** African-American women undergoing in vitro fertilization (IVF) had lower pregnancy rates, higher clinical pregnancy loss, and lower live birth rates, compared to Caucasian women. **Researchers urge African-American women not to wait to seek help when infertility is suspected or following two or more miscarriages.**

[Look inside for abstracts on both papers >>>](#)

Shady Grove Fertility Research Team for Prize Papers



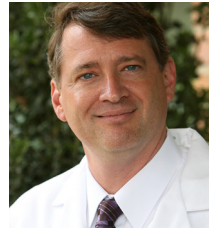
KATE DEVINE, M.D.



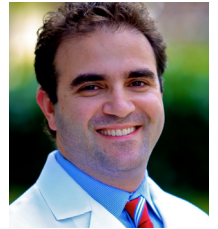
ERIC A. WIDRA, M.D.



KEVIN RICHTER, PH.D.



JEFFREY L. MCKEEBY, M.D.



ISAAC E. SASSON, M.D.



# Optimizing Medication, Reducing Injections

Three-Arm Randomized Controlled Trial: Vaginal Only Progesterone is Inferior, but Vaginal Plus Intramuscular (IM) Progesterone Every Third Day is Equivalent to Daily IM Progesterone for Vitrified Warmed Blastocyst Transfer in Terms of Live Birth  
 Kate Devine, M.D., Kevin Richter, Ph.D., Eric A. Widra, M.D., Jeffrey L. McKeeby, M.D.

 Scientific Congress Prize Paper Award Winner



## THE STUDY

Patients in the study received one of three different progesterone replacement protocols for their frozen embryo transfer (n=997 cycles).

- Via intramuscular injection only (IMP)
- Via vaginal suppositories
- Via a combination of IMP and vaginal suppositories

All frozen blastocyst-stage embryos transferred in the study were un-biopsied and high quality.

## THE RESULTS

There was a 40% reduction in live births in the progesterone suppository only patients while pregnancy and birth outcomes were equivalent for the IMP only and combination vaginal suppository and IMP patients.

## STUDY DETAILS

Patients who undergo in vitro fertilization (IVF) with a frozen embryo transfer are required to take daily progesterone replacement to prepare the uterus, enable an embryo to implant, and allow the pregnancy to continue. One current standard protocol for a frozen embryo transfer is progesterone via daily intramuscular injection (IMP).

While effective, published survey data have shown that these injections are associated with increased discomfort and anxiety for patients. The purpose of this study was to investigate whether patients could achieve similar live birth rates from FET, with few or even zero intramuscular progesterone injections.

Participants in the study were placed randomly into three groups. The first group used only intramuscular injections (IMP, 50mg progesterone in oil). The second group used only vaginal suppositories (Endometrin 200mg), and the third group used vaginal suppositories (Endometrin 200mg) paired with an intramuscular injection every third day (50mg progesterone in oil).

All patients underwent transfers of un-biopsied, high quality embryo(s) at the blastocyst stage. Primary outcome was live birth per transfer. Secondary outcomes included pregnancy (positive hCG 2 weeks after transfer), clinical pregnancy (ultrasound confirmation of intrauterine gestational sac 4-5 weeks after transfer), biochemical pregnancy losses, and clinical pregnancy losses.

During the planned interim analysis performed once half of the patients completed their final visit, it was discovered that there were significantly lower pregnancy rates in the patients using vaginal progesterone (Endometrin) only. This arm of the study was then unblinded and enrollment was discontinued.

The remaining arms of the study demonstrated that the patients using fewer intramuscular progesterone injections paired with vaginal progesterone had live birth rates per transfer equivalent to the patients receiving more frequent intramuscular injections only. This presents an exciting option to reduce injections by two-thirds while still providing patients optimal chances of having a baby via frozen embryo transfer (FET).

## FOR YOUR PATIENTS

For patients undergoing frozen embryo transfers (FET), they now have the option of a protocol that requires 2/3 fewer progesterone injections.

### Outcomes by Treatment Arm among Cycles Completed per Protocol

	IMP only	Endometrin + IMP	Endometrin only	Overall Chi-square (p val)	IMP only vs. Endometrin only (p val)	IMP only vs. Endometrin + IMP (p val)	IM + Endometrin vs Endometrin only (p val)
<b>Vitrified Blastocyst Transfers (N)</b>	<b>399</b>	<b>388</b>	<b>210</b>				
Positive hCG per transfer (%)	68.9	64.9	59.0	0.05	0.015	0.24	0.15
Biochemical loss per positive hCG (%)	17.1	13.1	33.1	<0.0001	<0.0001	0.20	<0.0001
Clinical pregnancy per transfer (%)	57.1	56.4	39.5	<0.0001	<0.0001	0.84	<0.0001
Pregnancy loss per clinical pregnancy (%)	14.9	18.7	27.7	0.036	0.01	0.28	0.09
Total pregnancy loss per positive hCG (%)	29.5	29.4	51.6	<0.0001	<0.0001	0.98	<0.0001
<b>Live birth per transfer (%)</b>	<b>48.6</b>	<b>45.9</b>	<b>28.6</b>	<b>&lt;0.0001</b>	<b>&lt;0.0001</b>	<b>0.44</b>	<b>&lt;0.0001</b>

# African-American Women Encouraged to Seek Fertility Care Sooner

African-American Patients Experience Reduced Pregnancy, Higher Pregnancy Loss, and Lower Live Birth from In Vitro Fertilization (IVF) Embryo Transfers Despite Producing More Oocytes and More Transfer Quality Embryos than Comparable Caucasian Patients **LA Bishop, M.D., Kate Devine, M.D., Isaac E. Sasson, M.D., Ph.D., TC Plowden, MJ Hill, M.D., AH DeCherney, M.D., Kevin Richter, Ph.D.**

## Health Disparities Special Interest Group Prize Paper Winner

### THE STUDY

More than 35,000 cycles of over 22,000 Caucasian and African-American patients between 2004 and 2016 were studied.

All patients underwent fresh autologous IVF cycles.

### THE RESULTS

African-American women respond just as well to medications that stimulate egg production, produce as many eggs, and actually produce more good quality embryos than Caucasian patients. Conversely, African-American women had lower pregnancy rates, higher clinical pregnancy loss, and lower live birth, suggesting uterine factors are a likely cause of decreased success.

### STUDY DETAILS

Multiple prior published studies have demonstrated that African-American women experience lower pregnancy rates, higher pregnancy loss, and lower live birth rates from in

vitro fertilization (IVF). In this study, SGF evaluated more than 35,000 IVF cycles of more than 22,000 Caucasian and African-American patients to better understand why African-American women experienced poorer IVF outcomes.

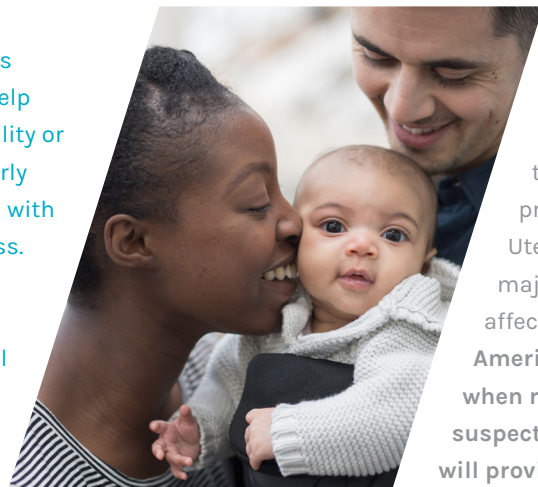
Participants in the study were SGF patients undergoing fresh IVF cycles between 2004 and 2012. Retrieval cycles for women self-identifying as Caucasian (n=29,547) and African American (n=6,670) were reviewed.

African-American women responded better to IVF stimulation than comparable Caucasian women, with higher serum estradiol, thicker endometria, more oocytes, and more surplus high-quality blastocysts available after fresh embryo transfer. Despite these advantages, clinical pregnancy was 9% lower, clinical pregnancy loss was 24% higher, and live birth was 14% lower for African Americans relative to comparable Caucasians. Uterine factors are the likely cause of this disparity, suggesting potential future research.

	Caucasian	African American	P-value	Caucasian (adj.)	African American (adj.)	P-value
Serum estradiol at trigger (pg/mL)	2221	2465	<0.0001	2209	2574	<0.0001
Endometrial thickness at trigger (mm)	11.6	11.9	<0.0001	11.6	11.9	<0.0001
Oocytes retrieved	13.7	13.7	NS	13.5	14.5	<0.0001
Mature (MII) oocytes	10.3	9.4	<0.0001	10.7	10.7	NS
Fertilized (2pn)	7.9	7.2	<0.0001	7.7	7.6	NS
Embryos per transfer	2.0	2.0	NS	2.0	2.0	NS
Cryopreserved blastocysts	1.2	1.4	<0.0001	1.2	1.6	<0.0001
Positive hCG per transfer	57.8%	49.7%	<0.0001	57.5%	52.4%	<0.0001
Clinical pregnancy per transfer	49.0%	42.0%	<0.0001	48.6%	44.3%	<0.0001
Clinical pregnancy loss	18.2%	26.1%	<0.0001	17.7%	21.9%	<0.0001
Live birth per transfer	40.0%	31.0%	<0.0001	38.8%	33.3%	<0.0001

### FOR YOUR PATIENTS

African-American patients should not wait to seek help when experiencing infertility or recurrent miscarriage. Early referrals provide patients with the best chance of success. In addition, annual OB/GYN examinations are critical to detect potential uterine problems in their earliest, easy to treat state.



### IMPACT ON PRETERM BIRTH

A related study from the same research team showed that singleton births among African-American IVF patients occur almost a week earlier, and are three times more likely to be preterm (28-32 weeks) or very preterm births (<28 weeks) compared with Caucasians. Uterine factors such as fibroids are most likely to be a major contributor to these outcomes and disproportionately affect African-American women. **Given this insight, African-American women should see a fertility specialist sooner when recurrent pregnancy loss occurs or infertility is suspected. Early intervention and treatment of uterine issues will provide patients with the best chance of success.**

## Optimizing Care through Research

### ASRM 2018: SGF Studies Impacting Your Patients

For the majority of Shady Grove Fertility patients, their successful treatment starts with you, and your timely referral to one of our providers. The trust between SGF and over 2,000 referring physicians every year is the reason why over 50,000 SGF babies have been born over the last quarter century. We are honored and humbled by your continued support.

Look inside for an in-depth view into some of SGF's recent award-winning research presented at the American Society for Reproductive Medicine's (ASRM) 2018 Scientific Congress & Expo. Our commitment to research and innovation means improved outcomes for your patients.



Shady Grove Fertility's landmark research earns ASRM's **TOP SCIENTIFIC CONGRESS PRIZE PAPER AWARD.**

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*Refer Your Patients with Confidence*

**SHADY GROVE FERTILITY**

