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| **PROTOCOL TITLE: Kidney/Pancreas Post Transplant: Immunosuppression in Pregnancy** |
| **APPLICABLE FACILITIES:** (Check all that apply) [x] EUH [ ] EUOSH [ ] EWWH [ ] EUHM [ ] EJCH [x] ESJH [x] TEC [ ] ESA [ ] ERH |
| **EFFECTIVE DATE:** Click here to enter a date. | **ORIGINATION DATE: 03/11/2019** |

**SCOPE:** All transplant program physicians, practitioners and clinical staff members are responsible for compliance with this clinical protocol.

**PURPOSE:** This protocol provides guidelines on the immunosuppressant regimen to be prescribed to patients who are becoming or already are pregnant post-kidney or kidney/pancreas transplant

**PROTOCOL:** The Emory Transplant Center and all the solid organ transplant programs will comply with all applicable federal, state, and local laws, regulations, policies and protocols regarding the management of transplant patients.

**TRANSPLANT CONSIDERATIONS IN PREGNANCY**

Maternal-Fetal Medicine (MFM) consult will be recommended prior to conception for medical management in conjunction with the transplant team.

Patients should be educated on and are encouraged to participate in Transplant Pregnancy Registry International©. <https://www.transplantpregnancyregistry.org/>.

**TARGET PATIENT POPULATIONS**

Recommended criteria for women to become pregnant post-kidney or kidney/pancreas transplant:

1. >2 years post-transplant
2. No history of rejection within 1 year
3. Stable serum creatinine and good renal function (SCr <1.5; no/minimal proteinuria)
4. Blood pressure <140/90
	* Patient should be transitioned off ACEI/ARB with stable blood pressure prior to conception
5. No acute infections
6. Stable immunosuppression
7. CMV/PCP prophylaxis complete

**BELATACEPT-BASED IMMUNOSUPPRESSION**

1. Tacrolimus overlap must be complete 6 months prior to conception
2. Belatacept to be continued as per protocol
	1. Dose should be adjusted monthly as weight changes throughout pregnancy
3. Mycophenolate mofetil to be transitioned to azathioprine (1-2mg/kg/day) 6 months prior to conception
4. Prednisone to be continued as per protocol

**TACROLIMUS-BASED IMMUNOSUPPRESSION**

1. Tacrolimus dosing and schedule to be continued as per protocol
	1. Increased monitoring may be required due to change in patient volume of distribution
2. Mycophenolate mofetil to be transitioned to azathioprine (1-2mg/kg/day) 6 months prior to conception
3. Prednisone to be continued as per protocol

**OTHER MEDICATIONS**

1. Patients should be transitioned off all medications contraindicated in pregnancy, including but not limited to:
	1. Angiotensin-converting enzyme inhibitors (ACEIs)
	2. Angiotensin II receptor blockers (ARBs)
	3. HMG-CoA reductase inhibitors (statins)
2. Other medications continued throughout pregnancy should be considered with input from MFM to determine risk versus benefit.

**PERIPARTUM**

1. Patients should remain off mycophenolate mofetil throughout peripartum period
	1. May transition from azathioprine to mycophenolate mofetil after breast feeding has been discontinued
2. Patients should remain off ACEI/ARB and/or statins throughout peripartum period until breast feeding is discontinued
3. Other medications continued throughout the peripartum period should be considered with input from MFM to determine risk versus benefit.

**IMMUNOSUPPRESSION EFFECTS ON MALE FERTILITY**

1. There is no firm evidence of harm to fertility or pregnancy outcomes with paternal exposure to immunosuppressive agents (belatacept, tacrolimus, mycophenolate mofetil, prednisone)

**RELATED DOCUMENT(S)/LINK(S):**

N/A

**DEFINITIONS:** *(If applicable)*

N/A

**REFERENCES AND SOURCES OF EVIDENCE:**

Hou S. Pregnancy in renal transplant recipients. Adv Chronic Kidney Dis. May 2013;20(3):253-9.

Constantinescu S, Pai A, Coscia LA, et al. Breast-feeding after transplantation. Clin Obstet Gynecol. 2014;28:1163-73.

Vijayan M, Pavlakis M. Pregnancy and the kidney transplant recipient. Curr Opin Nephrol Hypertens. Nov 2017;26(6):494-500.

Chittka D, Hutchinson JA. Pregnancy after renal transplantation. Transplantation. Apr 2017;101(4):675-8.

Shah S, Verma P. Overview of pregnancy in renal transplant patients. Int J Nephrol. 2016;1-7.

Combs J, Kagan A, Boelkins M, et al. Belatacept during pregnancy in renal transplant recipients. Am J Transplant. 2018;18:2079-82.

Kumar M, Ray L, Vemuri S, et al. Pregnancy outcomes following exposure to abatacept during pregnancy. Arthritis Rheum. 2015;45:351-6.

Mouyis M, Flint JD, Giles IP. Safety of anti-rheumatic drugs in men trying to conceive: a systemic review and analysis of published evidence. Arthritis Rheum. 2018;0:1-10.

**KEY WORDS:** Pregnancy, immunosuppression, conversion

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