

Appendix 1: Search strategy and data abstraction form [posted as supplied by author]

Search Strategy

Database: Embase Classic+Embase <1947 to 2014 March 05>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

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- 1 Prograf.ti.ab. (602)
 - 2 Cellcept.tw. (2811)
 - 3 Myfortic.tw. (520)
 - 4 Neoral.tw. (5384)
 - 5 gengraf.tw. (160)
 - 6 Rapamune.tw. (1507)
 - 7 mycophenolic acid delayed release.tw. (0)
 - 8 Drugs, Generic/ (12249)
 - 9 generic.tw. (61271)
 - 10 or/1-9 (76022)
 - 11 Tacrolimus/ (63292)
 - 12 tacrolimus.tw. (28711)
 - 13 Mycophenolic Acid/ or mycophenolate mofetil.tw. (27000)
 - 14 Cyclosporine/ (90309)
 - 15 (Cyclosporine or Ciclosporin).tw. (62527)
 - 16 Sirolimus/ (47640)
 - 17 Sirolimus.tw. (14972)
 - 18 brand name\$.tw. (3182)
 - 19 or/11-18 (214342)
 - 20 10 and 19 (9511)
 - 21 organ transplantation/ or exp heart transplantation/ or exp kidney transplantation/ or liver transplantation/ or exp lung transplantation/ (421784)
 - 22 ((organ or kidney or renal or heart or cardiac or liver or hepatic or lung or pulmonary) adj2 (transplant\$ or graft\$)).tw. (366639)
 - 23 21 or 22 (488772)
 - 24 20 and 23 (5265)
 - 25 limit 24 to yr="1980 - 2014" (5259)
 - 26 25 use prmz (1058) Medline**

 - 27 prograf.ti.ab. (602)
 - 28 Cellcept.ti.ab. (481)
 - 29 Myfortic.ti.ab. (171)
 - 30 Neoral.ti.ab. (2205)
 - 31 gengraf.ti.ab. (19)
 - 32 Rapamune.ti.ab. (256)
 - 33 mycophenolic acid delayed release.ti.ab. (0)
 - 34 *generic drug/ (6271)
 - 35 generic.tw. (61271)
 - 36 or/27-35 (66509)
 - 37 tacrolimus/ (63292)
 - 38 Tacrolimus.tw. (28711)

- 39 mycophenolic acid 2 morpholinoethyl ester/ (33579)
- 40 (mycophenolate mofetil or Mycophenolic acid).tw. (20317)
- 41 cyclosporin/ (90309)
- 42 (Cyclosporine or Ciclosporin).tw. (62527)
- 43 Sirolimus.tw. (14972)
- 44 brand name\$.tw. (3182)
- 45 or/37-44 (194781)
- 46 36 and 45 (4869)
- 47 organ transplantation/ or heart transplantation/ or kidney transplantation/ or liver transplantation/ or lung transplantation/ (401807)
- 48 ((organ or kidney or renal or heart or cardiac or liver or hepatic or lung or pulmonary) adj2 (transplant\$ or graft\$)).tw. (366639)
- 49 47 or 48 (482876)
- 50 46 and 49 (2430)
- 51 limit 50 to yr="1980 - 2014" (2424)
- 52 **51 use emczd (1380) Embase**

- 53 26 or 52 (2438)
- 54 remove duplicates from 53 (1559)

Search was repeated September 4th, 2014

Data abstraction form

Generic Immunosuppressant Review: Data Abstraction Form

Reviewer's Initials: _____ Reference ID Number _____

Lead Author: _____

Journal: _____ Year: _____

Language of Publication: 1. English 2. Other (specify) _____

Country(ies) of Study Origin: _____ Lebanon _____

Immunosuppressants Compared in the Study

Trade Name

Generic (record specific name of generic,
ie Tacrobell)

1. Prograf
2. Cellcept
3. Neoral

1. tacrolimus
2. mycophenolic acid
3. cyclosporine (microemulsion)

Patients Included in the Study

Transplant Organ: Lung Liver Kidney Pancreas Heart

Other: _____

New Transplants: yes no

Pediatric

Adult

Type of Study

Experimental

1. Randomized parallel group trial
2. Cross over trial
3. Planned before/after (ie investigators switched the drug)
4. Other: _____

Observational

1. Cohort, prospective
2. Cohort, retrospective

3. Before/after prospective
4. Before/after retrospective
5. Other (specify)_____

For before/after studies, was there one to one dose conversion (y/n) _____
 Were dose titrations allowed (y/n) _____
 Were target drug levels reported in the study? _____

If the study has more than one relevant time period, please record data for both/all

Drug Dosages and Monitoring

If not reported, write n/a

Generic Drug Group

Dose or weight normalized dose (circle one): Mean (SD) or Median (IQR)
 (circle one)

_____ (time period _____) p value _____

_____ (time period _____) p value _____

_____ (time period _____) p value _____
 (record units)

Number of patients requiring a change in dosage: _____

Dose increased _____ Dose decreased _____

Drug level: How specifically was drug level reported (ie dose normalized level, trough, C2)? _____

Mean (SD) or Median (IQR) (circle one)

_____ (time period _____) p value _____

_____ (time period _____) p value _____

_____ (time period _____) p value _____
 (record units)

Trade Name Drug Group

Dose or weight normalized dose (circle one): Mean (SD) or Median (IQR)

(circle one)

_____ (time period _____)

_____ (time period _____)

_____ (time period _____)

(record units)

Number of patients requiring a change in dosage: _____

Drug level: How specifically was drug level reported? _____

Mean (SD) or Median (IQR) (circle one) _____ (record units)

_____ (time period _____)

_____ (time period _____)

_____ (time period _____)

(record units)

Outcomes

If more than one relevant time period or type of transplant, record that data above the table and fill in one table for each time period and/or type of transplant

Please report data for all continuous variables as Mean (+/- Standard Deviation)

Variable	Generic group	Trade Name group	P value	Total	Follow up time
Subjects enrolled (n)					
Subjects analyzed (n)					
Men/Women					
Age					
Acute rejection (n)					
Graft loss (n)					
Infection (n)					
Death (n)					

Please report data for all continuous variables as Mean (+/- Standard Deviation)

Variable	Generic group	Trade Name	P value	Total	Follow up time
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		group			
Subjects enrolled (n)					
Subjects analyzed (n)					
Men/Women					
Age					
Acute rejection (n)*					
Graft loss (n)					
Infection (n)					
Death (n)					

*Record how this was defined (ie biopsy proven)

Renal Function

If more than one relevant time period or type of transplant, record that data above the table and fill in one table for each time period and/or type of transplant

Please report data for all continuous variables as Mean (+/- Standard Deviation)

Variable	Generic group	Trade Name group	Follow up time*	P value
Absolute creatinine (units)				
Absolute eGFR				

Please report data for all continuous variables as Mean (+/- Standard Deviation)

Variable	Generic group	Trade Name group	Follow up time	P value
Absolute creatinine (units)				
Absolute eGFR				

For Bioequivalence Studies Only

Please report data for all continuous variables as Mean (+/- Standard Deviation)

Variable	Generic group	Trade Name group	P value
AUC ()*			
C _{max}			
T max			
C ₀			

*(record time period)

C_{\max} mean ratio (90% CI) _____ AUC mean ratio (90% CI) _____

C_0 mean ratio (90% CI) _____

Quality Assessment

For RCT's, fill out the Cochrane Risk of Bias Assessment Tool

Wells et al. criteria for observational studies