

# Does conversion from Mycophenolate Mofetil (CellCept) to Enteric-coated Mycophenolate Sodium (Myfortic) improve gastrointestinal symptoms in pediatric renal transplant recipients?

<b>Submission date</b> 12/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/10/2008	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

# Study information

## Scientific Title

## Acronym

Myfortic

## Study objectives

To determine whether pediatric renal transplant recipients experience any difference in their gastrointestinal symptoms when converted from Mycophenolate MoFetil (MMF or CellCept) to Enteric-coated Mycophenolate Sodium (EC-MPS or Myfortic). Also, to evaluate the pharmacokinetics of MycoPhenolic Acid (MPA) in a subgroup of children converting from Cellcept to Myfortic.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University of British Columbia Clinical Research Ethics Board, approved on 27 November 2007 (ref: H06-03867)

## Study design

Non-randomised controlled trial.

## Primary study design

Interventional

## Study type(s)

Not Specified

## Health condition(s) or problem(s) studied

Kidney transplant

## Interventions

Once consent has been obtained from the participants, they will be asked to complete the validated Gastrointestinal Symptom Rating Scale (GSRS), a 15-item instrument designed to assess the symptoms associated with common gastrointestinal disorders. A subgroup of patients (10 participants) will participate in the pharmacokinetic evaluations.

Intervention: Switch those currently taking MMF (orally) to EC-MPS/ Myfortic (orally) for 6 months. The dose of EC-MPS for each participant will be determined according to the dose of MMF he has been taking.

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome(s)**

To determine whether pediatric renal transplant recipients experience any difference in their gastrointestinal symptoms when converted from MMF (CellCept) to EC-MPS (Myfortic) at 6 months.

**Key secondary outcome(s)**

To evaluate safety and efficacy of converting pediatric renal transplant patients from MMF to EC-MPS.

Specifically evaluating:

1. The incidence of adverse events within the study period
2. Renal function as determined by serum creatinine and estimated or nuclear Glomerular Filtration Rate (GFR) within the study period
3. Incidence of infections
4. Graft and patient survival within the study period

**Completion date**

01/12/2008

**Eligibility****Key inclusion criteria**

1. Children, 7-20 years of age, with renal transplant whose current immunosuppression includes MMF
2. Female patients of childbearing age who agree to maintain effective birth control practice during the study
3. Patient has a functioning renal transplant for at least 3 months and with stable renal function
4. The patient, or in case the patient is minor, the patient's parent(s) or their legal representative, has been fully informed and has given written informed consent to participate in the study. If the minor is in the position to comprehend the nature, significance and scope of the study and to determine his decision accordingly, then his written consent shall also be required. Witnessed informed consent is accepted in case the patient (if not a minor) is capable of making the decision but not capable of signing the document.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

7 years

**Upper age limit**

20 years

**Sex**

All

## **Key exclusion criteria**

1. Current maintenance immunosuppression does not include Mycophenolate Mofetil
2. The patient has developmental delay or a syndrome that would not allow him or her to complete the GSRs questionnaire
3. Patient with malignancy or history of malignancy
4. Gastrointestinal symptoms not related to MMF (i.e. Infectious diarrhea)
5. Patient has significant, uncontrolled concomitant infections or other serious medical conditions (For example, uncontrolled diabetes or peptic ulcers)
6. Patient is participating or has participated in another clinical trial and/or is taking or has been taking an investigational drug in the past 28 days

## **Date of first enrolment**

01/12/2006

## **Date of final enrolment**

01/12/2008

## **Locations**

### **Countries of recruitment**

Canada

### **Study participating centre**

**BC Children's Hospital**

Vancouver, B.C.

Canada

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## **Sponsor information**

### **Organisation**

Novartis Pharmaceuticals Canada Inc.

### **ROR**

<https://ror.org/05afs3z13>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Novartis Phamarceuticals Canada Inc (Canada)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration