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

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

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Not Specified

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
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.

### Secondary outcome measures
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

### Overall study start date
01/12/2006

### 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

### Age group
Child

### Lower age limit
7 Years

### Upper age limit
20 Years

### Sex
Both

### Target number of participants
32

### 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.
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## Sponsor information

### Organisation
Novartis Pharmaceuticals Canada Inc.

### Sponsor details
385 Bouchavrd Blvd.
Dorval
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H9S 1A9

### Sponsor type
Industry

### ROR
https://ror.org/05afs3z13

## Funder(s)

### Funder type
Industry

### Funder Name
Novartis Phamarceuticals Canada Inc (Canada)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration