

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

Submission date 12/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/01/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/10/2008	Condition category 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

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 hypothesis

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

Condition

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

Overall study end date

01/12/2008

Eligibility

Participant 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

Participant 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

Recruitment start date

01/12/2006

Recruitment end date

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.

Sponsor details

385 Bouchavrd Blvd.

Dorval

Quebec

Canada

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