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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 11/01/2008	**Overall study status** Completed	
Last Edited 09/10/2008	**Condition category** 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.
Canada
V6H 3V4

Sponsor information

Organisation
Novartis Pharmaceuticals Canada Inc.

Sponsor details
385 Bouchavrd Blvd.
Dorval
Quebec
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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