ForPatients
by Roche

Cardiac TransplantRenal TransplantAutoimmune Disorder

The Mycophenolate Pregnancy Registry

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT01733082 ML22679

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

The Mycophenolate Pregnancy Registry

Trial Summary:

The Mycophenolate Pregnancy Registry is designed as a prospective, observational registry collecting data regarding mycophenolate exposure during pregnancy, and pregnancy outcomes, fetal and infant outcomes after exposure. Early and later term pregnancy outcomes will be solicited at selected gestational time points. Structural and functional birth defects identified in the perinatal period through one year of life will be collected and classified. This is a non-proprietary registry and is a component of a comprehensive pregnancy Risk Evaluation and Mitigation Strategy (REMS) plan required by the FDA for all mycophenolate-formulations, including CellCept, Myfortic and any generic formulations.

Genentech, Inc.
Sponsor

N/A
Phase

NCT01733082 ML22679
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	lblAllAges	No

Inclusion Criteria:

- Pregnancy and reported maternal exposure to mycophenolate during pregnancy or within 6 weeks of discontinuing treatment

Exclusion Criteria:

- Pregnancies for which there is paternal exposure only
- Pregnancies occurring outside the U.S.