

Autoimmune Disorder

The Mycophenolate Pregnancy Registry

Trial Status
Recruiting

Trial Runs In
1 Countries

Trial Identifier
NCT01733082 ML22679

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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
Female

Age
1 to All Ages

Healthy Volunteers
No
