Detection and Characterization of Host Defense Defects

NCT00001355

Status	RECRUITING
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	3,600 participants

Key Eligibility Criteria

Inclusion (5)

• Patients known to have or suspected of having an immune defect significantly or primarily involving the phagocytes will be eligible for enrollment, as well as their blood relatives. Such syndromes include but are not limited to those listed above. Eligibility will not be limited based on sex, race, or disability. Patients or patient relatives must be over 1 month of age.

• The patient and patient relative cohorts will include the following special populations:

• Children: Children are included in this study because immune defects may present in early childhood, and early diagnosis or characterization may benefit subjects.

• Decisionally impaired adults: Patients and patient relatives will be able to provide informed consent for themselves or if they lack the capacity to provide informed consent, the study team will obtain consent from the legally authorized representative. Patients with underlying immune disorders, autoimmune phenomena or severe infections may sometimes present with delirium, encephalopathy, or coma and are therefore unable to provide informed consent. Excluding patients who are unable to provide consent could adversely impact patient access to medical therapy at the NIH as well as adversely impact research recruitment. Excluding patients unable to provide consent would also essentially prohibit us from evaluating patients at higher risk for adverse outcomes and therefore skew our understanding of disease. Similarly, enrolled patient subjects who lose the ability to provide ongoing consent during study participation may continue in the study. The risks and benefits of participation for subjects unable to consent should be identical to those described for less vulnerable patients. The process for obtaining consent for these individuals is described below.

• Healthy volunteers will be healthy adults between the age of 18 and 80 years of either sex, and they must be able to provide informed consents for themselves.

Exclusion (2)

• The presence of an acquired abnormality which leads to immune defects, such as HIV, cytotoxic chemotherapy or malignancy, could be grounds for possible exclusion if, in the opinion of the investigator, the presence of such disease process interfered with evaluation.

• Individuals with dementia that impairs obtaining informed consent are excluded from enrolling as healthy volunteers, although such subjects may enroll in the patient or relative cohorts if consent can be obtained as described below.

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States