

Longitudinal Observational Study on the Course of Cystic Fibrosis Lung Disease in Patients Following Newborn Screening

NCT02270476

Status RECRUITING
Sponsor Heidelberg University
Enrollment 200 participants

Key Eligibility Criteria

Inclusion (4)

- Newly diagnosed patients with Cystic Fibrosis (CF). Diagnosis of CF: at least one of the following three international accepted criteria is fulfilled: i) sweat chloride ≥ 60 mEq/L and/or ii) 2 CF-causing mutations in the CFTR gene and/or iii) changes typical for CF in the transepithelial potential difference in nasal or rectal epithelium.
- Age and mode of diagnosis:
- Early diagnosed (ED): Initial diagnosis following CF-NBS or for other reasons in the first 4 months of life (in preterms corrected age of 4 months) after January 1st, 2006. Other reasons could be prenatal diagnostics, meconium ileus or positive family history.
- Late diagnosed (LD): Diagnosed after the fourth month of life due to clinical symptoms; initial diagnosis after January 1st, 2006.

Exclusion (12)

- All patients are excluded who themselves or whose parents do not want to participate or that withdraw from the study; or those in whom the diagnosis of CF is unsure.
- Preterms < 30 th week of gestation
- Longer period of mechanical ventilation in first 3 months of life
- A significant medical disease or condition other than CF likely to interfere with the child's ability to complete the entire protocol
- Previous major surgery except for meconium ileus or atresia of the intestine
- ... and 7 more (see full listing online)

Locations (4 total)

University Children's Hospital Heidelberg, Cystic Fibrosis Centre, Heidelberg, Baden-Wuerttemberg, Germany
University Hospital Gießen and Marburg GmbH, Giessen, Hesse, Germany
Medizinische Hochschule Hannover, Hanover, Lower Saxony, Germany
... and 1 more locations