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 = glossary definition

Fontan 2 Study Basics

The Fontan Follow-up (Fontan 2) Study is a follow-up study to the [Fontan 1 Study](#). The target number is up to 546 children who were enrolled in the Fontan Study and are now in the age range of 12 to 25 years of age. The accrual period is approximately one year with recruitment to begin in November 2009.

Study Design

A follow-up of the Fontan cohort.

Primary Endpoint

Change (from Fontan 1 to Fontan 2) in the Physical Functioning Summary Score of the Child Health Questionnaire Parent Form (CHQ PF50).

Secondary Endpoints

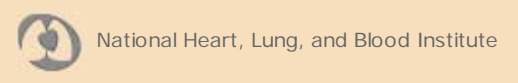
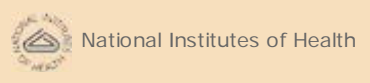
1. Change (from Fontan 1 to Fontan 2) in the Physical Functioning Scale of the Child Health Questionnaire Child Self-Report Form (CHQ CF87)
2. Current vital and cardiac transplantation status
3. Current functional health status/quality of life
4. Access to appropriate health care and related resources (transition to adult congenital heart specialist for older patients, time since last cardiologist visit, health care coverage, use of health care and related services)
5. Self-reported availability for and willingness to participate in future study activities

Inclusion Criteria

1. Enrollment in the Fontan 1 Study
2. Informed consent of subject and/or parent(s) or legal guardian, depending on subject's age

Exclusion Criteria

1. Patients enrolled in the original Fontan 1 Study who have died or had a cardiac transplant since the Fontan 1 study will be identified for the vital and transplant status outcome and collection of medical history data will be performed up to the time of death or transplant. These subjects will be excluded from the other study endpoints.



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