

A Study of Efgartigimod IV in Participants From 12 Years to Less Than 18 Years of Age With Chronic Immune Thrombocytopenia (ITP)

NCT07194850

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	argenx
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (6)

- Is aged 12 to less than 18 years when completing the informed consent process
 - Has a documented duration of primary ITP of more than 12 months on the date the informed consent process is complete
 - Has documented prior ITP treatment with at least 1 of the following treatments: corticosteroids, IVIg, anti-D immunoglobulin, thrombopoietin receptor agonist (TPO-RAs), or rituximab.
 - Has documented prior response, defined as 1 platelet count of $\geq 50 \times 10^9/L$ to at least 1 of the following ITP treatments: prednisone, other or nonspecified corticosteroids, IVIg, or anti-D immunoglobulin
 - Has documented insufficient response to a prior ITP treatment with corticosteroids, IVIg, anti-D immunoglobulin, TPO-RAs, rituximab, or splenectomy
- ... and 1 more (see full listing online)

Exclusion (4)

- Secondary ITP according to the following definition by the International Working Group (IWG): all forms of immune-mediated thrombocytopenia except primary ITP
- Nonimmune thrombocytopenia
- ITP-associated critical or severe bleeding
- History of hereditary thrombocytopenia

Locations (8 total)

Gaslini Children's Hospital, Genova, Italy
Uniwersytecki Szpital Dzieciocy w Lublinie, Lublin, Poland
Institutul Clinic Fundeni, Bucharest, Romania
... and 5 more locations