Study of Ianalumab Versus Placebo in Addition to First-line Corticosteroids in Primary Immune Thrombocytopenia (ITP)

Last Update: Jun 27, 2025
A Phase III, Randomized, Double-blind Study of Ianalumab (VAY736) Versus Placebo in Addition to First-line Corticosteroids in Primary Immune Thrombocytopenia (VAYHIT1)
ClinicalTrials.gov Identifier:
NCT05653349
Novartis Reference Number:CVAY736I12301
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to evaluate the effect of two different doses of ianalumab versus placebo in addition to first-line corticosteroids in maintaining platelet count ≥30 G/L in adult participants with primary ITP. This is a multi-center, randomized, double-blind Phase 3 study to assess the efficacy and safety of two different doses of ianalumab compared to placebo in adults with primary ITP (platelets count \<30 G/L) who require first-line standard-of-care corticosteroids.

After completion of the screening period, the participants will enter the randomized treatment period (ianalumab/placebo with standard of care corticosteroids).

After the treatment period, all participants will enter the follow-up period to be monitored for efficacy and safety or safety only depending on how they respond to the study treatment.

Condition
Primary Immune Thrombocytopenia (ITP)
Phase
Phase3
Overall Status
Recruiting
Number of Participants
225
Start Date
Mar 06, 2023
Completion Date
Dec 18, 2028
Gender
All
Age(s)

18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Corticosteroids

Oral or parental (if clinically justified)
Biological

Ianalumab

Intravenous infusion, prepared from concentrate solution
Drug

Placebo

Intravenous infusion, prepared from matching placebo

Eligibility Criteria

Inclusion Criteria:

* Signed informed consent prior to participation in the study.
* Male or female participants aged 18 years and older on the day of signing informed consent
* Primary ITP diagnosed within 3 months before initiating first-line ITP therapy (corticosteroids, IVIG)
* Platelet count below 30 G/L before starting any first-line ITP therapy (corticosteroids, IVIG)
* Response (platelet count \>=50 G/L) to corticosteroids (+/- IVIG) at any time prior to randomization. Note: Platelet count measured within 7 days of platelet transfusion will not be considered as response.

Key Exclusion Criteria:

* Evans syndrome or any other cytopenia (patients with low grade anemia related to bleeding or iron deficiency are eligible)
* Current life-threatening bleeding
* Previous ITP treatment, including splenectomy, except for corticosteroids and/or IVIG initiated as first-line therapy for up to 28 days before randomization and rescue corticosteroids and/or IVIG given prior to confirmed diagnosis of primary ITP .
* Prior use of B-cell depleting therapy (e.g., rituximab).
* Absolute neutrophil count below 1.0 G/L at randomization
* Participants with concurrent coagulation disorders and/or receiving anti-platelet or anticoagulant medication with an exemption of low dose of acetylsalicylic acid

Other protocol-defined Inclusion/Exclusion may apply.

Argentina

Novartis Investigative Site

Recruiting

Caba,Buenos Aires,C1280aeb,Argentina

Novartis Investigative Site

Recruiting

Caba,Buenos Aires,C1414drk,Argentina

Novartis Investigative Site

Recruiting

Ciudad Autonoma de Bs As,Buenos Aires,C1015abo,Argentina

Novartis Investigative Site

Recruiting

Bahia Blanca,Buenos Aires,B8000aat,Argentina

Novartis Investigative Site

Recruiting

Tucuman,San Miguel De Tucuman,4000,Argentina

Novartis Investigative Site

Recruiting

Buenos aires,C1039aac,Argentina

Novartis Investigative Site

Recruiting

Cordoba,5000,Argentina

Australia

Novartis Investigative Site

Recruiting

Wooloongabba,Queensland,4102,Australia

Novartis Investigative Site

Recruiting

Clayton,Victoria,3168,Australia

Novartis Investigative Site

Recruiting

Melbourne,Victoria,3004,Australia

Novartis Investigative Site

Recruiting

Canberra,Australian Capital Territory,2605,Australia

Austria

Novartis Investigative Site

Recruiting

Innsbruck,Tyrol,6020,Austria

Novartis Investigative Site

Recruiting

Wien,1140,Austria

Belgium

Novartis Investigative Site

Recruiting

Brugge,8000,Belgium

Novartis Investigative Site

Recruiting

Leuven,3000,Belgium

Novartis Investigative Site

Recruiting

Roeselare,8800,Belgium

Novartis Investigative Site

Recruiting

Brasschaat,2930,Belgium

Bulgaria

Novartis Investigative Site

Recruiting

Plovdiv,4002,Bulgaria

Novartis Investigative Site

Recruiting

Sofia,1413,Bulgaria

Novartis Investigative Site

Recruiting

Sofia,1431,Bulgaria

China

Novartis Investigative Site

Recruiting

Beijing,Beijing,100044,China

Novartis Investigative Site

Recruiting

Shijiazhuang,050000,China

Novartis Investigative Site

Recruiting

Changsha,Hunan,410008,China

Novartis Investigative Site

Recruiting

Kunming,Yunnan,650101,China

Novartis Investigative Site

Recruiting

Chongqing,Chongqing,400010,China

Novartis Investigative Site

Recruiting

Tianjin,300020,China

Novartis Investigative Site

Recruiting

Changzhou,Jiangsu,213004,China

Novartis Investigative Site

Recruiting

Hangzhou,Zhejiang,310003,China

Novartis Investigative Site

Recruiting

Guangzhou,Guangdong,510515,China

Novartis Investigative Site

Recruiting

Nanchang,Jiangxi,330006,China

Novartis Investigative Site

Recruiting

Hangzhou,Zhejiang,310006,China

Novartis Investigative Site

Recruiting

Shenzhen,Guangdong,518037,China

Novartis Investigative Site

Recruiting

Xian,Shaanxi,710004,China

Novartis Investigative Site

Recruiting

Bengbu,233004,China

Novartis Investigative Site

Recruiting

Luoyang,Henan,471003,China

Novartis Investigative Site

Recruiting

Taiyuan,Shanxi,030001,China

Novartis Investigative Site

Recruiting

Dalian,116000,China

Novartis Investigative Site

Recruiting

Zhengzhou,Henan,450052,China

Novartis Investigative Site

Recruiting

Chengdu,Sichuan,610041,China

Novartis Investigative Site

Recruiting

Jinan,250012,China

Novartis Investigative Site

Recruiting

Wuhan,Hubei,430022,China

Czechia

Novartis Investigative Site

Recruiting

Ostrava,Poruba,708 52,Czechia

Novartis Investigative Site

Recruiting

Brno Bohunice,625 00,Czechia

Novartis Investigative Site

Recruiting

Praha 10,100 34,Czechia

Novartis Investigative Site

Recruiting

Praha,12808,Czechia

France

Novartis Investigative Site

Recruiting

Caen,14033,France

Novartis Investigative Site

Recruiting

Rennes,35000,France

Novartis Investigative Site

Recruiting

Chambery cedex,73011,France

Novartis Investigative Site

Recruiting

Le Mans,72000,France

Novartis Investigative Site

Recruiting

Lille,59037,France

Novartis Investigative Site

Recruiting

Paris,75014,France

Germany

Novartis Investigative Site

Recruiting

Giessen,35392,Germany

Novartis Investigative Site

Recruiting

Jena,07740,Germany

Novartis Investigative Site

Recruiting

Frankfurt am Main,Hessen,60590,Germany

Novartis Investigative Site

Recruiting

Dresden,01307,Germany

Novartis Investigative Site

Recruiting

Essen,45147,Germany

Hong Kong

Novartis Investigative Site

Recruiting

New Territories,Hong Kong

Hungary

Novartis Investigative Site

Recruiting

Budapest,H-1083,Hungary

Novartis Investigative Site

Recruiting

Debrecen,4032,Hungary

India

Novartis Investigative Site

Recruiting

Ahmedabad,Gujarat,380013,India

Novartis Investigative Site

Recruiting

Mumbai,Maharashtra,400012,India

Novartis Investigative Site

Recruiting

Kolkata,West Bengal,700094,India

Novartis Investigative Site

Recruiting

Rishikesh,Uttarakhand,249203,India

Italy

Novartis Investigative Site

Recruiting

Vicenza,VI,36100,Italy

Novartis Investigative Site

Recruiting

Bologna,BO,40138,Italy

Novartis Investigative Site

Recruiting

Firenze,FI,50134,Italy

Novartis Investigative Site

Recruiting

Roma,RM,00168,Italy

Novartis Investigative Site

Recruiting

Trieste,TS,34129,Italy

Japan

Novartis Investigative Site

Recruiting

Okayama city,Okayama,701-1192,Japan

Novartis Investigative Site

Recruiting

Osaka-city,Osaka,543-8555,Japan

Novartis Investigative Site

Recruiting

Nagakute-city,Aichi,480-1195,Japan

Novartis Investigative Site

Recruiting

Iruma-gun,Saitama,350-0495,Japan

Novartis Investigative Site

Recruiting

Gifu shi,Gifu,500 8513,Japan

Novartis Investigative Site

Recruiting

Chiba,260-0852,Japan

Novartis Investigative Site

Recruiting

Shibukawa-city,Gunma,377-0280,Japan

Novartis Investigative Site

Recruiting

Fukuoka,815-8555,Japan

Novartis Investigative Site

Recruiting

Sapporo,Hokkaido,060-8604,Japan

Novartis Investigative Site

Recruiting

Matsumoto-city,Nagano,399-8701,Japan

Malaysia

Novartis Investigative Site

Recruiting

Johor Bahru,80100,Malaysia

Novartis Investigative Site

Recruiting

Kuala Lumpur,56000,Malaysia

Novartis Investigative Site

Recruiting

Penang,10050,Malaysia

Novartis Investigative Site

Recruiting

Selangor,68000,Malaysia

Novartis Investigative Site

Recruiting

Kuching,Sarawak,93586,Malaysia

Mexico

Novartis Investigative Site

Recruiting

Ciudad De Mexico,Mexico CP,14080,Mexico

Novartis Investigative Site

Recruiting

Mexico,Distrito Federal,06726,Mexico

Novartis Investigative Site

Recruiting

Morelia,Michoacan,58260,Mexico

Novartis Investigative Site

Recruiting

Monterrey,Nuevo Leon,64460,Mexico

Norway

Novartis Investigative Site

Recruiting

Gralum,1714,Norway

Romania

Novartis Investigative Site

Recruiting

Bucharest,030171,Romania

Novartis Investigative Site

Recruiting

Bucuresti,013975,Romania

Singapore

Novartis Investigative Site

Recruiting

Singapore,119074,Singapore

Novartis Investigative Site

Recruiting

Singapore,169608,Singapore

Novartis Investigative Site

Recruiting

Singapore,S308433,Singapore

Spain

Novartis Investigative Site

Recruiting

Sevilla,Andalucia,41013,Spain

Novartis Investigative Site

Recruiting

Salamanca,Castilla Y Leon,37007,Spain

Novartis Investigative Site

Recruiting

Barcelona,Catalunya,08035,Spain

Novartis Investigative Site

Recruiting

Madrid,28009,Spain

Novartis Investigative Site

Recruiting

Madrid,28046,Spain

Novartis Investigative Site

Recruiting

Murcia,30008,Spain

Thailand

Novartis Investigative Site

Recruiting

Bangkok,10330,Thailand

Novartis Investigative Site

Recruiting

Bangkok,10700,Thailand

Novartis Investigative Site

Recruiting

Chiang Mai,50200,Thailand

Turkey

Novartis Investigative Site

Recruiting

Istanbul,34214,Turkey

Novartis Investigative Site

Recruiting

Izmir,35100,Turkey

Novartis Investigative Site

Recruiting

Samsun,55139,Turkey

Novartis Investigative Site

Recruiting

Istanbul,TUR,34098,Turkey

Novartis Investigative Site

Recruiting

Aydin,09100,Turkey

Novartis Investigative Site

Recruiting

Edirne,22030,Turkey

United Kingdom

Novartis Investigative Site

Recruiting

Liverpool,L7 8xp,United Kingdom

Novartis Investigative Site

Recruiting

London,Sw17 0qt,United Kingdom

Novartis Investigative Site

Recruiting

London,W12 0hs,United Kingdom

Novartis Investigative Site

Recruiting

Truro,Cornwall,Tr1 3lj,United Kingdom

Novartis Investigative Site

Recruiting

Nottingham,Ng5 1pb,United Kingdom

Novartis Investigative Site

Recruiting

Birmingham,B15 2th,United Kingdom

Novartis Investigative Site

Recruiting

Southampton,So16 6yd,United Kingdom

Novartis Investigative Site

Recruiting

Glasgow,G31 2er,United Kingdom

Novartis Investigative Site

Recruiting

Leeds,Ls1 3ex,United Kingdom

United States

Clinical Research Alliance

Recruiting

Lake Success,New York,11042,United States

Jennifer Valentine

Phone: +1 516 488 2918#183
Email: jvalentine@researchcra.com

James D Olimpio

Inspira Medical Cent Mullica Hill

Recruiting

Mullica Hill,New Jersey,08062,United States

Erev Tubb

Catherine Vasquez

Phone: 856-641-7526
Email: VasquezC@ihn.org

INTEGRIS Cancer Institute of Oklahoma

Recruiting

Oklahoma City,Oklahoma,73142,United States

Kellie Larsen-Dyer

Email: Kellie.Larsen@integrisok.com

Basgar Alasad

University of Colorado Anschutz

Recruiting

Aurora,Colorado,80045,United States

Phone: 303-724-1695

George Gemlyn

Texas Oncology-Baylor Res Ins

Recruiting

Dallas,Texas,75204,United States

Dominique Marquez

Phone: +1 214 820 2687
Email: Dominique.marquez1@usoncology.com

Moshe Yair Levy

St Vincent Frontier Cancer Center

Recruiting

Billings,Montana,59102,United States

Patrick Cobb

Amanda Klein

Phone: 406-238-6290
Email: amanda.klein@imail.org

Yuma Regional Medical Center

Recruiting

Yuma,Arizona,85349,United States

Abhinav Chandra

Amy Olmeda

Email: amyolmeda@yumaregional.org

Massachusetts General Hospital

Recruiting

Boston,Massachusetts,02114,United States

Hanny Al-Samkari

Nicole Ciccolo

Email: nciccolo@mgh.harvard.edu

Hematology Oncology Association of Rockland

Recruiting

Nyack,New York,10960,United States

Marion VanWoudenberg

Phone: 845-362-1750
Email: research@highlandmedicalpc.com

Sung Ho Lee

Uni of Chi Medi Ctr Hema and Onco

Recruiting

Chicago,Illinois,60637,United States

Michael Drazer

Sara Moellering

Phone: 773-834-0783
Email: smoellering@bsd.uchicago.edu

Mays Cancer Ctr Uthsa Mdacc

Recruiting

San Antonio,Texas,78229,United States

Elizabeth Bowhay-Carnes

Cleveland Clinic Foundation

Recruiting

Cleveland,Ohio,44195,United States

Alan Lichtin

Antonio Wilson

Phone: 216-445-2572
Email: wilsona3@ccf.org

Napa Research

Recruiting

Margate,Florida,33063,United States

Emilio Araujo-Mino

Texas Oncology

Recruiting

McAllen,Texas,78503,United States

Nereida Salinas

Email: Nereida.Salinas@usoncology.com

Nurul Wahid

Community Cancer Institute

Recruiting

Clovis,California,93611,United States

Kelly Meehan

Phone: 559-387-1850

Email: Kmeehan@communitymedical.org

Mohammed Bukari

University of Pennsylvania

Recruiting

Philadelphia,Pennsylvania,19104,United States

Adam Cuker

Emmanuel Ndukwudimma

Phone: 215-614-4408
Email: emmanuel.ndukwudimma@pennmedicine.upenn.edu

Mayo Clinic Rochester

Recruiting

Rochester,Minnesota,55905,United States

Phone: 507-284-2467

Alexandra Wolanskyj

Oncology Care Associates

Recruiting

Bethesda,Maryland,20817,United States

Natalie Bongiorno

Phone: 301-897-1503
Email: natalie.bongiorno@aoncology.com

Ralph V Boccia

STAT Research Inc

Recruiting

Dayton,Ohio,45402,United States

Charles Bane

Derek Tipton

Email: Derek@StatResearch.net

Michigan Center of Medical Research

Recruiting

Farmington Hills,Michigan,48334,United States

Faisal Musa

Community Cancer Trials of Utah

Recruiting

Ogden,Utah,84405,United States

Carl Gray

Jenny Flores

Phone: 801-689-3909
Email: jenny@communitycancertrials.com

Compassionate Care Res Group Inc

Recruiting

Fountain Valley,California,92708,United States

Phone: 714-210-2300

Eric Lee

Rhode Island Hospital

Recruiting

Providence,Rhode Island,02903,United States

Phone: 401-444-5212

Andrew Hsu

Beth Israel Deaconess Medical Cente

Recruiting

Boston,Massachusetts,02215,United States

Janine Morrissey

Phone: 617-667-7000
Email: jmorriss@bidmc.harvard.edu

Rushad Patell

Metro Minnesota CCOP

Recruiting

Saint Louis Park,Minnesota,55416,United States

Yan Ji

Vietnam

Novartis Investigative Site

Recruiting

Ho Chi Minh,738000,Vietnam

Novartis Investigative Site

Recruiting

Hanoi,100000,Vietnam

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111
Email:

Novartis Pharmaceuticals

Phone: 1-888-669-6682
Email: novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05653349*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT05653349
2. #trial-eligibility
3. tel:+1 516 488 2918#183
4. mailto:jvalentine@researchcra.com
5. tel:856-641-7526
6. mailto:VasquezC@ihn.org
7. mailto:Kellie.Larsen@integrisok.com
8. tel:303-724-1695
9. tel:+1 214 820 2687
10. mailto:Dominique.marquez1@usoncology.com
11. tel:406-238-6290
12. mailto:amanda.klein@imail.org
13. mailto:amyolmeda@yumaregional.org
14. mailto:nciccolo@mgh.harvard.edu
15. tel:845-362-1750

16. mailto:research@highlandmedicalpc.com
17. tel:773-834-0783
18. mailto:smoellering@bsd.uchicago.edu
19. tel:216-445-2572
20. mailto:wilsona3@ccf.org
21. mailto:Nereida.Salinas@usoncology.com
22. tel:559-387-1850
23. mailto:Kmeehan@communitymedical.org
24. tel:215-614-4408
25. mailto:emmanuel.ndukwudimma@pennmedicine.upenn.edu
26. tel:507-284-2467
27. tel:301-897-1503
28. mailto:natalie.bongiorno@aoncology.com
29. mailto:Derek@StatResearch.net
30. tel:801-689-3909
31. mailto:jenny@communitycancertrials.com
32. tel:714-210-2300
33. tel:401-444-5212
34. tel:617-667-7000
35. mailto:jmorriss@bidmc.harvard.edu
36. tel:+41613241111
37. mailto:
38. tel:1-888-669-6682
39. mailto:novartis.email@novartis.com