

Secukinumab Open Label Roll-over Extension

Protocol

Last Update: Nov 15, 2024

An Open-label, Multi-center Protocol for Patients Who Have Completed a Previous Novartis Sponsored Secukinumab Study and Are Judged by the Investigator to Benefit From Continued Secukinumab Treatment
ClinicalTrials.gov Identifier:

[NCT04638647](#)

Novartis Reference Number:CAIN457A02001B

[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 assess long term safety in participants who have completed a Novartis trial with secukinumab, have been judged by the investigator to benefit from continued treatment with secukinumab, and are unable to obtain the marketed secukinumab formulation.

Condition

Autoimmunity, Inflammation

Phase

Phase4

Overall Status

Recruiting

Number of Participants

715

Start Date

Dec 22, 2020

Completion Date

Feb 29, 2028

Gender

All

Age(s)

6 Years - (Child, Adult, Older Adult)

Interventions

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Secukinumab s.c. injection

Eligibility Criteria

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Inclusion Criteria:

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1. Signed informed consent must be obtained for adult participants before any assessment is performed.
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Written informed assent and parental permission (age as per local law) must be obtained for pediatric

participants before any assessment is performed. If participants reach age of consent (age as per local law) during the study, they will need to also sign the corresponding study informed consent(s).

2. Ability to communicate effectively with the investigator, to understand and willing to comply with the requirements of the study.

3. Participant has completed treatment per protocol in a Novartis study of secukinumab (unless otherwise specified in a parent study protocol). Participants, who derive benefit from the treatment with secukinumab but have not completed the treatment in certain parent studies, due to parent study termination by Novartis, may be eligible if the termination was due to reasons other than safety or lack of efficacy (technical / administrative reasons).

4. Participant is deriving benefit from secukinumab, investigator believes he/she would continue to derive benefit from secukinumab and the benefit outweighs the risk, based on the investigator's judgement.

5. Participant is unable to obtain access to the marketed secukinumab formulation per local prescription and/or reimbursement guidelines.

Exclusion Criteria:

1. Participant has prematurely discontinued study treatment in the parent protocol.

2. Women of childbearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using methods of contraception during the entire study or longer if required by locally approved prescribing information (e.g., in European Union (EU) 20 weeks).

Brazil

Novartis Investigative Site

Recruiting

Sao Jose do Rio Preto,15090 000,Brazil

Novartis Investigative Site

Recruiting

Salvador,BA,40150 150,Brazil

Novartis Investigative Site

Recruiting

Vitoria,ES,29055 450,Brazil

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Novartis Investigative Site

Recruiting

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Juiz de Fora,MG,36010 570,Brazil

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Novartis Investigative Site

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Recruiting

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Sao Paulo,SP,01244-030,Brazil

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Recruiting

Sao Paulo,SP,04266 010,Brazil

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Recruiting

Rio de Janeiro,20241-180,Brazil

Bulgaria

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Recruiting

Plovdiv,4002,Bulgaria

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Recruiting

Sofia,1431,Bulgaria

Novartis Investigative Site

Recruiting

Sofia,1784,Bulgaria

China

Novartis Investigative Site

Recruiting

Shenzhen,Guangdong,518020,China

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Urumqi,Xinjiang,830001,China

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Novartis Investigative Site

Recruiting

Beijing,Beijing,100044,China

Novartis Investigative Site

Recruiting

Yangzhou,Jiangsu,225001,China

Novartis Investigative Site

Recruiting

Shanghai,200127,China

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Recruiting

Wuhan,Hubei,430030,China

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Recruiting

Bengbu,233004,China

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KunMing,Yun Nan,650000,China

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Chongqing,Chongqing,400010,China

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Novartis Investigative Site

Recruiting

Changsha,Hunan,410011,China

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Recruiting

Wenzhou,Zhejiang,325000,China

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Recruiting

Xiamen,Fujian,361001,China

Novartis Investigative Site

Recruiting

Pingxiang,Jiangxi,337000,China

Novartis Investigative Site

Recruiting

Zhejiang,315016,China

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Recruiting

Baotou,Inner Mongolia,014010,China

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Recruiting

Beijing,100000,China

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Chang Chun,Jilin,130021,China

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Novartis Investigative Site

Recruiting

Hohhot,Inner Mongolia,10050,China

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Recruiting

Jinan,250012,China

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Recruiting

Guangzhou,Guangdong,510080,China

Novartis Investigative Site

Recruiting

Linyi,Shandong,276000,China

Novartis Investigative Site

Recruiting

Hefei,Anhui,230001,China

Novartis Investigative Site

Recruiting

Nanjing,Jiangsu,210008,China

Novartis Investigative Site

Recruiting

Shanghai,200040,China

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Shanghai,Guangdong,515041,China

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Chengdu,Sichuan,610041,China

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Recruiting

Hefei,Anhui,230601,China

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Recruiting

Nanjing,Jiangsu,210009,China

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Recruiting

Shanghai,200050,China

Colombia

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Recruiting

Bogota,110221,Colombia

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Recruiting

Cundinamarca,111121,Colombia

Novartis Investigative Site

Recruiting

Bucaramanga,Santander,0001,Colombia

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Recruiting

<!-- THEME DEBUG -->

Ibague,Tolima,730006,Colombia <!-- THEME HOOK: 'printable_pdf_footer' -->

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Czechia

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<!-- THEME DEBUG -->

Praha 11,14900,Czechia

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Recruiting

Praha 2,128 50,Czechia

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Recruiting

Praha 4,140 59,Czechia

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Recruiting

Ostrava,Czech Republic,772 00,Czechia

Novartis Investigative Site

Recruiting

Praha 5,150 06,Czechia

Novartis Investigative Site

Recruiting

Brno-Zidonice,CZE,61500,Czechia

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Recruiting

Uherske Hradiste,686 01,Czechia

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Recruiting

Hradec Kralove,CZE,500 05,Czechia

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Brno Bohunice,625 00,Czechia

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Guatemala

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Recruiting

Guatemala City,01010,Guatemala

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Recruiting

Guatemala,01001,Guatemala

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Recruiting

Guatemala,01009,Guatemala

India

Novartis Investigative Site

Recruiting

Nashik,Maharashtra,422101,India

Poland

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Recruiting

Warszawa,02 637,Poland

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Recruiting

Bialystok,15-351,Poland

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Recruiting

Sochaczew,96-500,Poland

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Recruiting

Torun,87-100,Poland

9/16

Russian Federation

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Recruiting

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Kazan, 420064, Russian Federation

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Novartis Investigative Site

Recruiting

Moscow, 119296, Russian Federation

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Recruiting

Saint Petersburg, 197198, Russian Federation

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Recruiting

Yaroslavl, 150003, Russian Federation

South Africa

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Recruiting

Panorama, Western Cape, 7500, South Africa

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Recruiting

Stellenbosch, 7600, South Africa

Spain

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Recruiting

Santiago De Compostela, Galicia, 15706, Spain

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Madrid, 28045, Spain

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Valencia,46026,Spain

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Switzerland

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Recruiting

St Gallen,9007,Switzerland

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Recruiting

Basel,4031,Switzerland

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ON OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.t
Phone: [304-256-0242](tel:304-256-0242)
Email: webb.catie421@gmail.com

11/16

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Daves Fretzin Clinical Rea Group

Recruiting

Indianapolis,Indiana,46256,United States

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Scott Fretzin

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Oregon Health Sciences University

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Portland,Oregon,97239,United States

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Atul Deodhar

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Denver Arthritis Clinic

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Suneet Grewal

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Hinsdale,Illinois,60521,United States

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Swarnika Sampat

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Accurate Clinical Research Inc

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Philip Waller

Viet Ta

Email: vta@accurateclinicalresearch.com

West Tennessee Research Institute

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Jackson,Tennessee,38305,United States

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Jacob A. Aelion

Kim Smith

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Phone: [731-664-7824](tel:731-664-7824)

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FL Medical Clinic Orlando Health

Recruiting

Zephyrhills,Florida,33542,United States

Endora Ankrah

Phone: [813-782-1234](tel:813-782-1234)

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Natalie Faith

Medvin Clinical Research

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Van Nuys,California,91405,United States

Samy Metyas

Homestead Assoc In Research Inc

Recruiting

Homestead,Florida,33033,United States

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Southwest Rheum Rsrch LLC

Recruiting

Mesquite,Texas,75150,United States

<!-- THEME DEBUG -->

Atul K Singhal

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Nancy De La Cruz

14/16

Phone: [972-288-2600](tel:972-288-2600)

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Email: ndelacruz@swrr.net

Recruiting

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West Hills, California, 91307, United States

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Lauren Jackson

Email: firoozcoordinator1@gmail.com

Nazanin Firooz

Worldwide Contacts

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

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Email:

Novartis Pharmaceuticals

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Source URL: <https://dev.arctic.novartis.com/clinicaltrials/study/nct04638647>

List of links present in page

1. <https://clinicaltrials.gov/ct2/show/NCT04638647>
2. [#trial-eligibility](#)
3. <tel:619-229-1995>
4. <mailto:evas@heartsmart.info>
5. <tel:304-256-0242>
6. <mailto:webb.catie421@gmail.com>
7. [tel:+1 317 516 5030#102](tel:+13175165030#102)
8. <mailto:jprusa@ecommunity.com>
9. <tel:810-953-8700>
10. <tel:954-476-2338>
11. <tel:814-693-0300>
12. <mailto:marybeyer@altoonaresearch.com>
13. <tel:503-494-5742>
14. <mailto:harryy@ohsu.edu>
15. [tel:+1 303 394 2828](tel:+13033942828)
16. <tel:510-357-1040>
17. <mailto:swarnnie@gmail.com>

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19. <tel:731-664-7824>

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20. <mailto:ksmith@arthritisclinic.org>

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22. <mailto:eankrah@floridamedicalclinic.com>

23. tel:305-246-0873
24. mailto:jgrullon@associatesinresearch.com <!-- THEME DEBUG -->
25. tel:972-288-2600 <!-- THEME HOOK: 'printable_pdf_header' -->
26. mailto:firoozcoordinator1@gmail.com ON TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->
27. mailto:firoozcoordinator1@gmail.com
28. tel:1-888-669-6682 ON TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->
29. mailto:
30. tel:1-888-669-6682
31. mailto:novartis.email@novartis.com

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