ISRCTN11424009 https://doi.org/10.1186/ISRCTN11424009

A Phase I, randomized, double-blind, three-group study in healthy participants to evaluate if there is similarity between the amount of study drug in the bloodstream after dosing, the safety of the study drug, any side effects that might be associated with it and laboratory tests of participants' blood after receiving either Bmab 1200, US Stelara or EU Stelara and to evaluate how the immune system may interact with these drugs

Submission date 16/02/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/04/2022	**Overall study status** Completed	
Last Edited 08/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The aim of this study is to compare the blood levels of the study drugs ustekinumab (Bmab) 1200, US-licensed Stelara (US Stelara), and EU-approved Stelara (EU Stelara) after a single subcutaneous (under the skin) injection in healthy volunteers.

Who can participate?
Healthy volunteers between 18 and 55 years of age

What does the study involve?
Potential participants will be screened to assess their eligibility to enter the study within 28 days before the dose administration. Participants will be admitted into the study site on Day -1 (the day before dosing) and will be confined to the study site until discharge on Day 10. Participants will return to the study site for follow-up visits up to Day 113 (± 2 days). Participants will be randomly allocated to receive a single dose of 45 mg of either US Stelara, EU Stelara, or Bmab 1200 on Day 1. Two groups of three participants (one Bmab 1200, one US Stelara, and one EU Stelara per cohort) will be dosed at least 24 hours apart and, providing no safety concerns arise,

the remaining participants will be dosed starting from at least 24 hours later. Safety data (including adverse effects, injection site reactions, electrocardiogram [ECG], vital signs, and physical examinations as available) will be reviewed after each group and continuation to dose the remaining participants will be at the investigator's discretion.

What are the possible benefits and risks of participating?
There are no benefits expected as this is a healthy volunteer study. Common adverse effects of Stelara include nasopharyngitis (inflammation of the nose and throat), upper respiratory tract infection, headache, fatigue, diarrhoea, back pain, dizziness, pharyngolaryngeal pain (sore throat), pruritus (itching), injection site erythema (rash) and myalgia (muscle pain).

Where is the study run from?
Phase I clinical trial units in the UK

When is the study starting and how long is it expected to run for?
February 2022 to January 2023

Who is funding the study?
Biocon (India)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-006630-39

Integrated Research Application System (IRAS)
1004851

Protocol serial number
BM12H-NHV-01-G-01

Study information

Scientific Title
A Phase I, randomized, double-blind, three-arm, parallel-design study in healthy subjects to evaluate pharmacokinetics, safety, tolerability, and immunogenicity of Bmab 1200 after a single subcutaneous injection in comparison with EU-approved Stelara® and US-licensed Stelara®

Study objectives
1. To establish pharmacokinetic (PK) equivalence between ustekinumab (Bmab) 1200 and US Stelara, Bmab 1200 and EU Stelara, and EU Stelara and US Stelara after a single 45 mg subcutaneous injection in healthy subjects
2. To further determine the PK of Bmab 1200, US Stelara, and EU Stelara
3. To evaluate the safety, tolerability, and immunogenicity of Bmab 1200 as compared to US Stelara and EU Stelara after a single 45 mg subcutaneous injection in healthy subjects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2022, London - Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)20 7104 8170; harrow.rec@hra.nhs.uk), ref: 22/FT/0012

Primary study design
Interventional

Study design
Randomized-controlled double-blind parallel-group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate to severe plaque psoriasis, psoriatic arthritis, Crohn’s disease and ulcerative colitis

Interventions
Participants will receive a single, subcutaneous (under the skin) 45 mg dose of either Bmab 1200, US Stelara or EU Stelara on one dosing occasion (Day 1). Some participants will receive Bmab 1200, some will receive US Stelara and others will receive EU Stelara, this will be block randomised on a 1:1:1 basis. The randomisation code will be produced using a computer-generated pseudo-random permutation procedure and code breaks will be maintained in sealed envelopes maintained at the study sites.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Ustekinumab

Primary outcome(s)
AUC0-inf and Cmax of the study drug following a single 45 mg subcutaneous injection. These will be calculated based on the PK blood samples. Sampling timepoints within 60 minutes predose and 12 hours postdose on Day 1, and on Days 2 (24 hours postdose), 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 21, 29, 36, 43, 50, 57, 64, 71, 85, and 113. PK will be measured by a validated PK method

Key secondary outcome(s)
1. AUC0-t, tmax, t1/2, kel, Vd/F, CL/F, and %AUCextrap of the study drug following a single 45 mg subcutaneous injection. These will be calculated based on the PK blood samples. Sampling timepoints within 60 minutes predose and 12 hours postdose on Day 1, and on Days 2 (24 hours postdose), 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 21, 29, 36, 43, 50, 57, 64, 71, 85, and 113. PK will be measured by a validated PK method.
2. Incidence and titer of anti-drug antibodies (ADA) to the study drug measured by a validated method within 60 minutes predose on Day 1 and on Days 7, 15, 29, 57, 85, and 113
3. Incidence and severity of adverse events (AEs) as reported from Day 1 until the follow-up visit
4. Incidence of laboratory abnormalities, based on hematology, clinical chemistry, and urinalysis test results as measured at screening, Day -1, and Days 2, 6, 10, 29, 57, 85, and 113
5. 12-lead ECG parameters measured at screening, Day -1, 4 hours postdose on Day 1, and Day 10 (prior to discharge), and Day 113
6. Vital signs measured at screening, Day -1, Day 1 (within 2 hours predose and at 1, 4, and 10 hours postdose), once daily from Days 2 to 10 and at each follow-up visit (including EOS)
7. Physical examinations: full physical examination performed at either screening or Day -1, and on Day 113, and symptom-directed examination performed at Days 2, 5, 7, 10, 12, 29, 64, and 85.

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Males or females, between 18 and 55 years of age, inclusive
2. For Japanese subjects only:
2.1. Must have Japanese parents and Japanese grandparents
2.2. Must not have lived outside Japan for >10 years
3. Body weight between 60.0 and 100.0 kg; however, for Japanese subjects, permissible body weight range will be between 55.0 and 100.0 kg
4. Body mass index between 18.0 and 30.0 kg/m², inclusive
5. In good health, determined by no clinically significant findings from medical history, 12-lead ECG, vital signs measurements, and clinical laboratory evaluations (congenital non-hemolytic hyperbilirubinemia [e.g., suspicion of Gilbert's syndrome based on total and direct bilirubin] is acceptable) at screening, check-in, and predose on Day 1 (where applicable) and from the physical examination at screening or check-in, as assessed by the investigator (or designee).
6. Females will not be pregnant (as confirmed by pregnancy testing at screening and check-in) or lactating, and females of childbearing potential and males will agree to use contraception
7. Should be a nonsmoker or light smoker, i.e smokes a maximum of five cigarettes (or three cigars or three pipe-full) or equivalent for e-cigarettes (10 puffs of an e-cigarette is considered equivalent to one combustible cigarette), or other tobacco- or nicotine-containing product per day; and ability and willingness to refrain from smoking from check-in until Day 2 and to limit smoking to five cigarettes per day from Day 3 through the end of study visit
8. Able to comprehend and willing to sign an ICF and abide by the study restrictions

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
258

Key exclusion criteria
1. Significant history or clinical manifestation of malignancy, or any metabolic, allergic, dermatological, hepatic, renal, hematological, pulmonary, cardiovascular, gastrointestinal, neurological, respiratory, endocrine, lymphatic disorder, immune system disorder, musculoskeletal, connective tissue, or psychiatric disorder, as determined by the investigator (or

designee)
2. History of significant hypersensitivity, intolerance, or allergy to any drug compound (specifically any biologic product or the constituents of Stelara, Bmab 1200, or hypersensitivity to host cell [murine myeloma cell or Chinese hamster ovary cells]derived proteins, latex), food, or other substance, unless approved by the investigator (or designee)
3. Positive hepatitis B or C panel and/or positive human immunodeficiency virus test
4. Any current active infections, including significant localized infections (eg, middle ear infections or ophthalmic infections), or any recent history (within 1 week prior to study drug administration) of active infections, cough or fever, or a history of recurrent or chronic infections
5. History of active tuberculosis (TB) or presence of active or latent TB. Positive result for QuantiFERON TB-Gold test at screening. Having resided or travelled in regions where TB and mycosis are endemic within 90 days before screening, or who intend to visit such a region during the period of 90 days after dosing.
6. Historical or planned major surgery within 12 weeks of dosing and during the study
7. Administration of a coronavirus disease 2019 (COVID-19) vaccine in the past 14 days prior to dosing or have the intention of receiving the COVID-19 vaccine within 14 days postdose
8. Received any vaccine within 4 weeks before screening or have the intention to receive a vaccination (with the exception of the COVID-19 vaccine) during the study. Subjects who have had Bacillus Calmette–Guérin (BCG) vaccination within 1 year prior to dosing. Subjects must agree not to receive a BCG vaccination during the study and through at least 1 year after dosing
9. Use or intend to use any medications/products known to alter drug absorption, metabolism, or elimination processes, including St. John's wort, within 30 days prior to dosing
10. Use or intend to use any prescription medications/products other than hormone replacement therapy (estrogen and progestogen), oral, implantable, transdermal, injectable, or intrauterine contraceptives within 14 days prior to dosing or slow-release medications/products considered to still be active within 14 days prior to check-in
11. Use or intend to use any nonprescription medications/products including vitamins, minerals, and phytotherapeutic/herbal/plant-derived preparations (other than St John's wort, which has been previously defined) within 7 days prior to check-in
12. Participation in a clinical study involving administration of an investigational drug(new chemical entity) in the past 90 days or 5 half-lives (whichever is longer), prior to dosing
13. Known history of previous exposure to ustekinumab or ustekinumab biosimilar, or any IL-12 or IL-23 monoclonal antibodies, approved or investigational
14. Alcohol consumption of >21 units per week for males and >14 units for females. One unit of alcohol equals ½ pint (285 ml) of beer or lager, one glass (125 ml) of wine, or 1/6 gill (25 ml) of spirits.
15. Positive alcohol breath test result or positive urine drug screen (confirmed by repeat)at screening or check-in
16. History of alcoholism or drug/chemical abuse within 2 years prior to check-in
17. Ingestion of poppy seed-containing foods or beverages within 7 days prior to check-in
18. Receipt of blood products within 2 months prior to check-in
19. Donation of blood from 3 months prior to screening, plasma from 2 weeks prior to screening, or platelets from 6 weeks prior to screening
20. Poor peripheral venous access
21. Subjects who, in the opinion of the investigator (or designee), should not participate in this study

Date of first enrolment
13/04/2022

Date of final enrolment

23/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Labcorp Clinical Research Unit Limited
Springfield House
Hyde Street
Leeds
United Kingdom
LS2 9LH

Study participating centre
Medicines Evaluations Unit
The Langley Bldg
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Roundthorn Industrial Estate
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Sponsor information

Organisation
Biocon (India)

ROR
https://ror.org/047kynf18

Funder(s)

Funder type
Industry

Funder Name
Biocon

Alternative Name(s)
Biocon Limited, Biocon Ltd

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
India

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/05/2025	08/05/2025	Yes	No
HRA research summary			28/06/2023	No	No