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A Phase I, double-blind, placebo-controlled, ascending single intravenous dose, safety, tolerability, pharmacokinetic and pharmacodynamic study in healthy participants and non-cystic fibrosis bronchiectasis patients colonized with Pseudomonas aeruginosa administered INFEX702

Submission date
03/02/2022

Recruitment status
No longer recruiting

Registration date
10/05/2022

Overall study status
Completed

Last Edited
28/01/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
There is an unmet medical need to develop effective maintenance treatments for the reduction of exacerbations in patients with Non-Cystic Fibrosis Bronchiectasis (NCFB) colonized with Pa; currently there are no approved drug therapies available in NCFB for the reduction of exacerbations. NCFB is a neglected, chronic condition that results in progressive respiratory decline typified by the irreversible permanent dilation of the airways, a chronic cough, overproduction of sputum, recurrent respiratory infections and chronic inflammation resulting in progressive lung damage. Patients have poor quality of life and many patients develop Pa infections, which worsen prognosis. Chronic or recurrent infection with Pa is associated with poorer pulmonary function, increased inflammation, higher hospitalization rates, higher healthcare costs, greater morbidity and mortality compared with other NCFB-associated pathogens, such as H. influenzae. Patients with Pa infections can suffer from multiple exacerbations every year; up to 8-12 per annum. The aetiology of NCFB is often unknown but can be the result of previous lung infections.

Who can participate?
Healthy volunteers aged 18 to 55 years and non-cystic fibrosis bronchiectasis patients aged 18 years and over.

What does the study involve?
Each participant will participate in 1 treatment period only, residing in the CRU from Day -1 (the day before dosing) to Day 5 (96 hours post-dose) for healthy volunteers; the residential period

for non-cystic fibrosis bronchiectasis patients is up to day 4 (72 hours post-dose). All participants will return for 11 outpatient appointments (2 of which can be by telephone) with a final follow-up visit on day 180.
Based on the ongoing blinded review of safety, tolerability and pharmacokinetic results, additional non-residential visits may be required. The number of additional non-residential visits will not exceed three per treatment period and will not extend beyond 28 days after the final follow-up visit.

What are the possible benefits and risks of participating?
Benefits:
There are no direct benefits to healthy participants taking part in the study. As this is a phase 1 study, it is not known if the trial drug will have a beneficial effect for the patients in Part B. It is hoped that the results of this study will help to inform how patients with Pseudomonas aeruginosa infections are treated in the future.
Risks:
Participants are in-patients during dose administration and closely monitored for signs of anaphylaxis, >96 hrs after (or 72 hours for PART B) . Drugs to treat anaphylaxis and Advanced Life Support equipment are available if needed.
Participants will be monitored and encouraged to report any local irritations around the infusion site.
Participants will be closely monitored for signs of enhanced inflammatory reaction with frequent observations and monitoring of vital signs.
Collecting blood may cause bruising, fainting, and in rare cases, infection.
The blood pressure cuff used to take your blood pressure may cause discomfort or bruising to your upper arm.
During the collection of nose/throat swabs, you may experience sneezing, retching and eye tearing. People who are susceptible to nose bleeds may experience one.
The ECG procedure may cause discomfort and/or bruising during the attachment and removal of the leads (sticky pads) to and from the skin, as well as irritation at the site of the lead application. In some cases, we may have to shave the area of the body where the sticky pads are attached to ensure that the pads stick to your body.
Bronchoscopy and Bronchoalveolar lavage: Minor complications, sore throat, hoarse voice, nose bleeds or irritation, mildly blood-tinged phlegm, fever or flu-like symptoms. Rarely (less than 1%), a chest infection can occur due to a bronchoscopy. More serious complications causing fatality are extremely rare, at less than 0.0002%.

Where is the study run from?
Royal Liverpool Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2022 to February 2026

Who is funding the study?
INFEX Therapeutics (UK)

Who is the main contact?
CRF.Contact@liverpoolft.nhs.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-005018-32

Integrated Research Application System (IRAS)
1004503

Study information

Scientific Title
A Phase I, double-blind, placebo-controlled, ascending single intravenous dose, safety, tolerability, pharmacokinetic and pharmacodynamic study in healthy participants and non-cystic fibrosis bronchiectasis patients colonized with Pseudomonas aeruginosa administered INFEX702

Acronym
INFEX-PROTECT 1

Study objectives
- To determine the safety and tolerability of ascending single intravenous doses of INFEX702 in healthy adult participants (Part A) and patients with Non-Cystic Fibrosis Bronchiectasis (NCFB) (Part B)
- To determine the single intravenous dose pharmacokinetics of INFEX702 in healthy participants (Part A) and NCFB patients (Part B)
- To assess the immunogenicity of INFEX702 in healthy participants and NCFB patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2022, North West - Greater Manchester Central Research Ethics Committee (3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048208; gmcentral.rec@hra.nhs.uk), ref: 22/NW/0048

Primary study design
Interventional

Study design

Interventional double-blind randomized placebo-controlled trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Respiratory infection

Interventions
Current interventions as 01/05/2025:
The study will be conducted in two parts (Part A: Healthy participants and Part B: patients with non-cystic fibrosis bronchiectasis). Subjects will be randomised to receive either active (Infex702) or placebo.
Part A
Part A will comprise a single-dose, sequential-cohort study. Healthy participants will be studied in 4 dose cohorts (A1 to A4). Each dose cohort will consist of 8 participants (6 active: 2 placebo per cohort).
The planned dose levels in Part A are:
A1 – 1 mg/kg
A2 – 3 mg/kg
A3 – 6 mg/kg
A4 – 10 mg/kg

Part B,
Part B will comprise a single ascending dose, sequential group study. 12 patients with NCFB will be studied in 2 cohorts (Group B1 and B2), each cohort consisting of 6 evaluable participants. In each of cohorts B1 and B2, 5 participants will receive INFEX702 and 1 will receive placebo.

Duration of treatment
Single intravenous administration of INFEX702 or placebo in all cohorts (Parts A and B).

Follow-up
Each subject will participate in 1 treatment period only, residing in the CRU from Day -1 (the day before dosing) to Day 5 (96 hours post-dose). In Part B, the residential period post-dose may be reduced from 96 hours to 72 hours post-dose, subject to satisfactory review of the safety and tolerability data by the DEC for Part A. All participants in Parts A and B will return for appointments on Days 5, 8, 15, 22, 29, 36, 43, 57, 71, 99, 106 and a final follow-up visit on day 180. Day 36 and 57 visits can be conducted as telephone contact interviews instead of outpatient appointments if agreed by the participant and study team

Randomisation process (online tool, sealed envelope)
A randomisation code will be produced using a computer-generated pseudo-random permutation procedure.
For each participant in the study, an individual sealed envelope (produced by Statistician) containing the randomisation code will be kept in a secure location to enable the Investigator to break the code for safety purposes

Previous interventions:
The study will be conducted in two parts (Part A: Healthy participants and Part B: patients with non-cystic fibrosis bronchiectasis). Subjects will be randomised to received either active (Infex702) or placebo.

Part A
Part A will comprise a single dose, sequential cohort study. Healthy participants will be studied in 4 dose cohorts (A1 to A4). Each dose cohort will consist of 8 participants (6 active: 2 placebo per cohort).
The planned dose levels in Part A are:
A1 – 1 mg/kg
A2 – 3 mg/kg
A3 – 6 mg/kg
A4 – 10 mg/kg

Part B,
Part B will comprise a single ascending dose, sequential group study. 12 patients with NCFB will be studied in 2 cohorts (Group B1 and B2), each cohort consisting of 6 evaluable participants. In each of cohorts B1 and B2, 5 participants will receive INFEX702 and 1 will receive placebo.

Duration of treatment
Single intravenous administration of INFEX702 or placebo in all cohorts (Parts A and B).

Follow-up
Each subject will participate in 1 treatment period only, residing in the CRU from Day -1 (the day before dosing) to Day 5 (96 hours post -dose). In Part B, the residential period post-dose may be reduced from 96 hours to 72 hours post-dose subject to satisfactory review of the safety and tolerability data by the DEC for Part A,. All participants in Parts A and B, will return for appointments on Days 5, 8, 15, 22, 29, 36, 43, 57, 71, 99 and a final follow up visit on day 106.

Randomisation process (online tool, sealed envelope)
A randomisation code will be produced using a computer-generated pseudo-random permutation procedure.
For each participant in the study, an individual sealed envelope (produced by Statistician) containing the randomisation code will be kept in a secure location to enable the Investigator to break the code for safety purposes

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
INFEX702

Primary outcome(s)
Current primary outcome measure as of 01/05/2025:
Safety measured by:
Incidence and severity of adverse events (AEs)

Previous primary outcome measure:
Timepoints for the evaluation of this end point for Part A would be the review of all available data per cohort (minimum subjects (6) - 96 hrs post dose) prior to dose escalation committee safety review.
For Part B the review of all available safety data and tolerability data up to (and including) a

minimum of 7 days (168 hours, D8) for each participant in each cohort prior to dose escalation committee safety review.
Safety and tolerability measured by:
1. Incidence and severity of adverse events (AEs) every study day
2. Physical examination findings follow up visit
3. Safety laboratory tests (clinical chemistry, haematology, coagulation, Urinalysis) : Days -1, 1 ,2 , 3 ,5,8,15,22,29,36,43,57,71,99, follow up
4. Vital sign measurements (blood pressure, heart rate, temperature, respiration rate and oxygen saturations) every study day
5. Electrocardiogram (ECG) every study day
6. Local tolerability (number of i.v. site reactions) (study days 1-3)

Key secondary outcome(s)
Current secondary outcome measures as of 01/05/2025:
1. Safety and tolerability measured by:
1.1. Physical examination findings Day 106 and follow-up visit Day 180
1.2. Safety laboratory tests (clinical chemistry, haematology, coagulation, urinalysis): Days -1, 1, 2, 3, 5, 8, 15, 22, 29, 36, 43, 57, 71, 99, 106 and day 180 follow-up
1.3. Vital sign measurements (blood pressure, heart rate, temperature, respiration rate and oxygen saturations) every study day
1.4. Electrocardiogram (ECG) every study day
1.5. Local tolerability (number of i.v. site reactions) (study days 1-3)

Previous secondary outcome measures:
Timepoints for the evaluation of this end point for Part A would be the review of all available data per cohort (minimum subjects (6) - 96 hrs post dose) prior to dose escalation committee review
For Part B the review of all available safety data and tolerability data up to (and including) a minimum of 7 days (168 hours, D8) for each participant in each cohort prior to dose escalation committee review
Pharmacokinetics of INFEX702 measured by calculating PK parameters from serum samples taken on every study day. Multiple samples will be taken on Day 1:
1. Area under the serum concentration-time curve from time 0 to infinity (AUC0-∞)
2. Area under the serum concentration-time curve from time 0 to 28 days post dose (AUC0-28d)
3. Area under the serum concentration-time curve from time 0 to the last observed quantifiable concentration (AUC0-t)
4. Serum concentration observed at 28 days post dose (C28d)
5. Maximum observed serum concentration (Cmax)
6. Apparent terminal half-life (t1/2)
7. Time of last quantifiable concentration (tlast)
8. Time of occurrence of Cmax (tmax)

Completion date
03/02/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/05/2025:
Part A:
1. Provision of signed and dated, written informed consent prior to any study-specific procedures

2. Participants must be willing and able to comply with trial requirements
3. Males and females aged 18 to 55 years inclusive at the time of providing consent
4. BMI between 18 and 32 kg/m2 (inclusive)
5. Weight less than or equal to 120kg
6. In good health as determined by a responsible and qualified physician (including confirmation from GP) and determined by:
6.1. Medical history
6.2. Physical examination
6.3. Vital signs assessment
6.4. 12-lead electrocardiogram (ECG)
6.5. Clinical laboratory evaluations (congenital non-haemolytic hyperbilirubinaemia is acceptable).
7. The Over-Volunteering Prevention System (TOPS) registration completed, and no conflict found
8. Women of childbearing potential (WOCBP) and fertile male participants who are sexually active with WOCBP must agree to use two methods of contraception (see section 10.9.2 for details) and refrain from donating ova or sperm. The duration of contraception will be from the first administration of trial treatment, throughout trial and up to 4 months after dosing. Post-menopausal women defined as no menses for 12 months without an alternative medical cause.

Part B:
Participants must comply with all of the following inclusion criteria to be eligible for the study:
1. Provision of signed and dated, written informed consent prior to any study-specific procedures
2. Participants must be willing and able to comply with trial requirements.
3. Male and female patients of ≥ 18 years of age at screening
4. BMI > 15.0 and < than or = 40.00 kg/m2 (inclusive)
5. Weight < than or = to 120 kg
6. Proven diagnosis of Non-Cystic Fibrosis bronchiectasis as documented by computed tomography (CT), or high-resolution CT reported by a radiologist and as assessed by the investigator
7. FEV1 ≥ 50% predicted at screening
8. A stable regimen for the management of exacerbations and maintenance (treatments unchanged for 28 days prior to randomization). Patients are allowed to be on inhaled antibiotics and/or oral macrolide assuming it is stable therapy for at least 3 months prior to visit 1.
9. Clinical or microbiological evidence of exacerbation within 5 years and Microbiological culture positive or PCR positive for P. aeruginosa from one or more respiratory specimen(s) taken within 42 days of randomization.
10. Able to expectorate sputum on the majority of days
11. Women of childbearing potential (WOCBP defined as all women physiologically capable of becoming pregnant) and fertile male participants who are sexually active with WOCBP must agree to use two methods of contraception (see section 10.9.2 for details) and refrain from donating ova or sperm. The duration of contraception will be from the first administration of trial treatment, throughout trial and up to 4 months after the last dose. Post-menopausal women defined as no menses for 12 months without an alternative medical cause.

Previous inclusion criteria:
Part A:
1. Provision of signed and dated, written informed consent prior to any study-specific procedures
2. Participants must be willing and able to comply with trial requirements
3. Males and females aged 18 to 55 years inclusive at the time of providing consent
4. BMI between 18 and 32 kg/m² (inclusive)
5. Weight less than or equal to 120 kg

6. In good health as determined by a responsible and qualified physician (including confirmation from GP) and determined by:
6.1. Medical history
6.2. Physical examination
6.3. Vital signs assessment
6.4. 12 lead electrocardiogram (ECG)
6.5. Clinical laboratory evaluations (congenital non haemolytic hyperbilirubinaemia is acceptable).
7. The Over-Volunteering Prevention System (TOPS) registration completed and no conflict found
8. Women of childbearing potential (WOCBP) and fertile male participants who are sexually active with WOCBP must agree to use two methods of contraception and refrain from donating ova or sperm. The duration of contraception will be from the first administration of trial treatment, throughout trial and up to 4 months after dosing. Post-menopausal women defined as no menses for 12 months without an alternative medical cause

Part B:
1. Provision of signed and dated, written informed consent prior to any study-specific procedures
2. Participants must be willing and able to comply with trial requirements.
3. Male and female patients of ≥18 years of age at screening
4. BMI between 15 and 40 kg/m² (inclusive)
5. Weight less than or equal to 120kg
6. Proven diagnosis of Non-Cystic Fibrosis bronchiectasis as documented by computed tomography (CT) or high-resolution CT and as assessed by the investigator
7. History of 2 or more exacerbations treated with oral antibiotics OR 1 or more exacerbation requiring parenteral antibiotic treatment within 18 months prior to screening.
8. FEV1 ≥30% predicted at screening
9. A stable regimen of local standard treatment for BE (treatments unchanged for 28 days prior to randomization).
10. Colonised with P. aeruginosa, defined as 2 or more consecutive positive cultures, collected at least 1 month apart within the last 18 months, with last culture collected within the last 12 months. Respiratory samples used can include: expectorated sputum; deep throat cough swab; oro-pharyngeal swab; bronchoalveolar lavage.
11. Able to expectorate sputum on the majority of days
12. Women of childbearing potential (WOCBP defined as all women physiologically capable of becoming pregnant) and fertile male participants who are sexually active with WOCBP must agree to use two methods of contraception and refrain from donating ova or sperm. The duration of contraception will be from the first administration of trial treatment, throughout trial and up to 4 months after the last dose. Post-menopausal women defined as no menses for 12 months without an alternative medical cause

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
41

Key exclusion criteria
Current exclusion criteria as of 01/05/2025:
Part A:
1. Female participants who are pregnant or currently lactating
2. Participants who do not agree, or whose partners of childbearing potential do not agree, to use appropriate contraception or to refrain from donating egg or sperm from the time of dosing until 4 months after the last dose of study drug.
3. Donated blood in the 3 months prior to screening, plasma in the 7 days prior to screening, platelets in the 6 weeks prior to screening (inclusion can be delayed under these circumstances)
4. Consume more than 28 units of alcohol per week or any significant history of alcohol /substance misuse as determined by the investigator
5. Current active smoker or ex-smoker (not stopped smoking within 4 weeks prior to Visit 1) with a history of smoking equivalent to >10 pack years
6. Unwilling to abstain from vigorous exercise for 48 hours prior to any study visit.
7. Unwilling to abstain from alcohol for 48 hours prior to any study visit.
8. Participants who have any clinically significant allergy or allergic condition as determined by the investigator (with the exception of non-active hay fever).
9. Participants who have any abnormality of vital signs prior to the first dose administration that, in the opinion of the investigator, would increase the risk of participating in the study.
10. Participants who have any clinically significant abnormal physical examination findings.
11. Participants who have any clinically significant 12-lead ECG abnormality that, in the opinion of the investigator, would increase the risk of participating in the study. This includes QTcB values >450ms (male) or >470ms (female), confirmed on triplicate ECG recordings from which the mean value will be derived.
12. Participants who have hepatitis B or C or are carriers of HBsAg or are carriers of HCV Ab or are positive for HIV 1/2 antibodies.
13. Any clinically significant abnormal finding on biochemistry, haematology, toxicology or serological blood tests, urinalysis, or clinical examination
• N.B. In the event of clinically significant abnormal test results, confirmatory repeat tests will be requested.
14. Taking concomitant medications (with the exception of up to 2g paracetamol daily or the oral contraceptive pill)
15. Received any medication that has required dose adjustment (with the exception of the OCP or paracetamol) within 14 days prior to the first dose administration.
16. Received any non-prescribed systemic or topical medication (including vaccination), herbal remedy or vitamin/mineral supplementation within 14 days prior to the first dose administration (with the exception of paracetamol)
17. Participants who have a positive alcohol breath test or a positive urine drug screen (a repeat assessment is acceptable).
18. Positive for SARS-CoV-2 on day of admission Day (-1).

19. Participation in another interventional study within 3 months or 5 half-lives, whichever is longer
20. Clinically significant medical history in the opinion of the Investigator.
21. Previously received mAbs, immunoglobulin or any blood products within the last 6 months
22. History of immune complex disease
23. Any other condition or consideration that, in the opinion of the Investigator, would pose a health risk to the participant if they were enrolled in the study, or would otherwise interfere with the evaluation of the study aims
24. Previously enrolled in this study
25. Participants who have any known hypersensitivity to any of the excipients of INFEX702
26. Received any vaccination, including for COVID-19, within 14 days prior to the first dose administration or any planned vaccination 14 days after the last dose of study medication.

Part B:
The participant may not enter the study if ANY of the following apply:
1. Diagnosis of cystic fibrosis.
2. Primary diagnosis of bronchial asthma (where, in the opinion of the investigator, the main reason for exacerbations/continuing therapy is due to asthma primarily and not due to P. aeruginosa relating to bronchiectasis)
3. Primary diagnosis of COPD associated with at least a 20 pack year smoking history (where, in the opinion of the investigator, the main reason for exacerbations/continuing therapy is due to COPD primarily and not due to P. aeruginosa relating to bronchiectasis)
4. Current smoker at screening or not stopped smoking (including VAPES) within 4 weeks prior to Visit 1.
5. Signs and symptoms of clinically significant acute pulmonary or non-pulmonary conditions with the exception of NCFB.
6. Positive for SARS-CoV-2 on day of admission Day (-1).
7. Any significant medical condition that is either recently diagnosed or was not stable during the last 3 months, other than pulmonary exacerbations, and that in the opinion of the investigator makes participation in the trial against the patients' best interests.
8. Any patient with lung cancer or a history of lung cancer.
9. Any patient with active cancer or a history of cancer with less than 5 years disease-free survival time (whether or not there is evidence of local recurrence or metastases) except completely treated in situ carcinoma of the cervix or completely treated and resolved nonmetastatic squamous or basal cell carcinoma of the skin. Localized basal cell or squamous cell carcinoma (without metastases) of the skin are acceptable. Patients with a history of cancer (excluding lung cancer) and 5 years or more disease-free survival time may be included.
10. Patients requiring long-term oxygen therapy for chronic hypoxemia. This is typically patients requiring oxygen therapy >15 h per day delivered by home oxygen cylinder or concentrator.
11. Patients who have had a pulmonary exacerbation requiring systemic glucocorticosteroid treatment and/or antibiotics in the 4 weeks prior to screening. In the event of an exacerbation occurring during the screening epoch, the patient must discontinue from the study. The patient may be rescreened once the inclusion/exclusion criteria have been met.
12. Patients with active pulmonary tuberculosis (defined by a positive QuantiFERON®-TB Gold Test).
13. Patients currently receiving treatment for non-tuberculous mycobacterial (NTM) pulmonary disease or with one or more positive cultures in the last 12 months for Mycobacterium. avium complex, M. abscessus complex, M. kansasii, M. malmoense, M. xenopi, M. simiae or M. chelonae, unless all subsequent NTM cultures (at least two) are negative and in the opinion of the investigator the patient does not meet ATS criteria for NTM-pulmonary disease.
14. Haemoptysis in 28 days prior to screening that is felt by investigator to be clinically significant and with a risk of interfering with their study participation'

15. Clinically significant laboratory abnormalities (not associated with the study indication) at screening.
16. Primary immunodeficiency receiving immunoglobulin therapy.
17. Patients with a history of or active allergic bronchopulmonary aspergillosis.
18. Diagnosed with an organ and bone marrow transplant/graft versus host disease.
19. Patients with haematological malignancies.
20. Patients with any condition that, in the opinion of the investigator or, after discussion with the medical monitor, will compromise the safety and well-being of the patient or the interpretability of the study data
21. Patients who are receiving systemic antibiotics for any indication, other than azithromycin for NCFB, within 28 days prior to study drug administration
22. Receiving any medication that may influence the response to treatment. Prohibited medications: immunomodulators (cyclosporine, tacrolimus, anti-TNF alpha, steroids >15mg/day, alpha 1 antitrypsin, methotrexate, azathioprine, immune globulins (IV or subcutaneous), Prolastin, anti-cytokines).
23. Systemic corticosteroids at >10 mg/day prednisolone equivalent for >14 days or pulse dose corticosteroids (2 -5 days) within 28 days prior to the administration of the study drug. Topical corticosteroids are allowed.
24. Initiation of treatment with chronic macrolide therapy within 3 months prior to study drug administration (participants may be taking chronic macrolide therapy at the time of enrolment into the study).
25. Use of any other investigational drug within 30 days prior to screening or 5 half-lives, whichever is longer
26. Previously received mAbs, immunoglobulin or any blood products within the last 6 months
27. Women who plan to become pregnant, are pregnant or nursing (lactating) women where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive urine human chorionic gonadotropin (hCG) laboratory test.
28. History or current diagnosis of clinically significant ECG abnormalities (QTcB >450 ms in males and > 470 ms in females) or concomitant medication indicating significant risk to cardiac safety for patients participating in the study
29. Any known or suspected hypersensitivity to, or known allergy to, or other intolerance to the study medication or placebo or the excipients.
30. A significant history of alcohol/substance misuse as determined by the investigator
31. Unwilling to abstain from vigorous exercise for 48 hours prior to any study visit.
32. Unwilling to abstain from alcohol for 48 hours prior to any study visit
33. Received any vaccination, including for COVID-19, within 14 days prior to the first dose administration or any planned vaccination 14 days after the last dose of study medication

Previous exclusion criteria:
Part A:
1. Female participants who are pregnant or currently lactating
2. Participants who do not agree, or whose partners of childbearing potential do not agree, to use appropriate contraception or to refrain from donating egg or sperm from the time of dosing until 4 months after the last dose of study drug.
3. Donated blood in the 3 months prior to screening, plasma in the 7 days prior to screening, platelets in the 6 weeks prior to screening (inclusion can be delayed under these circumstances)
4. Consume more than 28 units of alcohol per week or any significant history of alcohol /substance misuse as determined by the investigator
5. Current active smoker or ex-smoker (not stopped smoking within 4 weeks prior to Visit 1) with a history of smoking equivalent to >10 pack years (including vapes)
6. Unwilling to abstain from vigorous exercise for 48 hours prior to any study visit.
7. Unwilling to abstain from alcohol for 48 hours prior to any study visit.

8. Participants who have any clinically significant allergy or allergic condition as determined by the investigator (with the exception of non-active hay fever).
9. Participants who have any abnormality of vital signs prior to the first dose administration that, in the opinion of the investigator, would increase the risk of participating in the study.
10. Participants who have any clinically significant abnormal physical examination findings.
11. Participants who have any clinically significant 12-lead ECG abnormality that, in the opinion of the investigator, would increase the risk of participating in the study. This includes QTcB values >450ms (male) or >470ms (female), confirmed on triplicate ECG recordings from which the mean value will be derived.
12. Participants who have hepatitis B or C or are carriers of HBsAg or are carriers of HCV Ab or are positive for HIV 1/2 antibodies.
13. Any clinically significant abnormal finding on biochemistry, haematology, toxicology or serological blood tests, urinalysis or clinical examination. N.B. In the event of clinically significant abnormal test results, confirmatory repeat tests will be requested
14. Taking concomitant medications (with the exception of up to 2g paracetamol daily or the oral contraceptive pill)
15. Received any medication that has required dose adjustment (with the exception of the OCP or paracetamol) within 14 days prior to the first dose administration.
16. Received any non-prescribed systemic or topical medication, herbal remedy or vitamin /mineral supplementation within 14 days prior to the first dose administration (with the exception of paracetamol)
17. Participants who have a positive alcohol breath test or a positive urine drug screen (a repeat assessment is acceptable).
18. Positive for SARS-CoV-2 (using a polymerase chain reaction test)within 72 hours prior to admission.
19. Participation in another interventional study within 3 months or 5 half-lives, whichever is longer
20. Clinically significant medical history in the opinion of the Investigator.
21. Previously received mAbs, immunoglobulin or any blood products within the last 6 months
22. History of immune complex disease
23. Any other condition or consideration that, in the opinion of the Investigator, would pose a health risk to the participant if they were enrolled in the study, or would otherwise interfere with the evaluation of the study aims
24. Previously enrolled in this study
25. Participants who have any known hypersensitivity to any of the excipients of INFEX702
26. Received any vaccination, including for COVID-19, with 14 days prior to the first dose administration or any planned vaccination 14 days after the last dose of study medication

Part B:
1. History of cystic fibrosis.
2. Primary diagnosis of bronchial asthma.
3. Primary diagnosis of COPD associated with at least a 20 pack-year smoking history.
4. Current smoker at screening or not stopped smoking within 4 weeks prior to Visit 1.
5. Signs and symptoms of clinically significant acute pulmonary or non-pulmonary conditions with the exception of NCFB.
6. Positive for SARS-CoV-2 within 72 hours prior to admission
7. Any significant medical condition that is either recently diagnosed or was not stable during the last 3 months, other than pulmonary exacerbations, and that in the opinion of the investigator makes participation in the trial against the patients' best interests.
8. Any patient with lung cancer or a history of lung cancer.
9. Any patient with active cancer or a history of cancer with less than 5 years disease-free survival time (whether or not there is evidence of local recurrence or metastases). Localized

basal cell carcinoma (without metastases) of the skin is acceptable. Patients with a history of cancer (excluding lung cancer) and 5 years or more disease-free survival time may be included.
10. Patients requiring long-term oxygen therapy for chronic hypoxemia. This is typically patients requiring oxygen therapy >15 h per day delivered by home oxygen cylinder or concentrator.
11. Patients who have had a pulmonary exacerbation requiring systemic glucocorticosteroid treatment and/or antibiotics in the 4 weeks prior to screening. In the event of an exacerbation occurring during the screening epoch, the patient must discontinue from the study. The patient may be rescreened once the inclusion/exclusion criteria have been met.
12. Patients with active pulmonary tuberculosis (defined by a positive Quanteferon gold test).
13. Patients currently receiving treatment for non-tuberculous mycobacterial (NTM) pulmonary disease.
14. Patients with one or more positive cultures in the last 12 months for Mycobacterium. avium complex, M. abscessus complex, M. kansasii, M. malmoense, M. xenopi, M. simiae or M. chelonae, unless all subsequent NTM cultures (at least two) are negative and in the opinion of the investigator the patient does not meet ATS criteria for NTM-pulmonary disease
15. Haemoptysis of more than 60 mL at any time within 28 days prior to screening
16. Clinically significant laboratory abnormalities (not associated with the study indication) at screening.
17. Primary immunodeficiency receiving immunoglobulin therapy.
18. Patients with a history of primary ciliary dyskinesia.
19. Patients with a history of or active allergic bronchopulmonary aspergillosis.
20. Diagnosed with an organ and bone marrow transplant/graft versus host disease.
21. Patients with haematological malignancies.
22. Patients with other clinically significant conditions (not associated with the study indication) at screening which might interfere with the assessment of this study.
23. Patients who are receiving inhaled or systemic antibiotics for any indication, other than azithromycin for NCFB, within 28 days prior to study drug administration
24. Receiving any medication that may influence the response to treatment. Prohibited medications: immunomodulators (cyclosporine, tacrolimus, anti-TNF alpha, steroids >15 mg/day, alpha 1 antitrypsin, methotrexate, azathioprine, immune globulins (IV or subcutaneous), Prolastin, anti-cytokines).
25. Systemic corticosteroids at >10 mg/day prednisolone equivalent for >14 days or pulse dose corticosteroids (2 -5 days) within 28 days prior to the administration of the study drug. Topical corticosteroids are allowed
26. Initiation of treatment with chronic macrolide therapy within 28 days prior to study drug administration (participants may be taking chronic macrolide therapy at the time of enrolment into the study, but they must have initiated treatment more than 28 days prior to Visit study drug administration).
27. Use of any other investigational drug within 30 days prior to screening or 5 half-lives, whichever is longer
28. Previously received mAbs, immunoglobulin or any blood products within the last 6 months
29. Pregnant or nursing (lactating) women where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive human chorionic gonadotropin (hCG) laboratory test.
30. History or current diagnosis of ECG abnormalities or concomitant medication indicating significant risk of safety for patients participating in the study
31. Any known or suspected hypersensitivity to, or known allergy to, or other intolerance to the study medication or placebo.
32. Consume more than 28 units of alcohol per week or any significant history of alcohol /substance misuse as determined by the investigator
33. Unwilling to abstain from vigorous exercise for 48 hours prior to any study visit.
34. Unwilling to abstain from alcohol for 48 hours prior to any study visit

35. Participants who have any known hypersensitivity to any of the excipients of INFEX702
36. Received any vaccination, including for Covid-19, within 14 days prior to the first dose administration or any planned vaccination 14 days after the last dose of study medication

Date of first enrolment
10/10/2022

Date of final enrolment
29/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Liverpool Hospital
Clinical Research Facility
Ward 4C 4th Floor
Liverpool
England
L7 8XD

Sponsor information

Organisation
Infex Therapeutics

Funder(s)

Funder type
Industry

Funder Name
INFEX Therapeutics

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No