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An early-phase clinical study to provide early data on an inhibitor/blocker of an important part of the immune system in the lung

Submission date
09/11/2022

Recruitment status
No longer recruiting

Registration date
21/12/2022

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Interstitial lung disease (ILD) is an umbrella term used for a large group of diseases that cause scarring (fibrosis) in the lungs, inflammation in the lungs, or a mixture of both. The scarring causes stiffness in the lungs which makes it difficult to breathe and get oxygen to the bloodstream.

As there are more than 100 different types of ILD, it is difficult to monitor and treat these conditions effectively. Currently, the diagnosis of conditions involving fibrosis/scarring relies on a number of different measures, including lung biopsy, and available treatments following diagnosis are often limited. New potential drugs are in development to treat fibrotic conditions but in order for them to work effectively, we need to better understand how this process works and be able to see the effects treatments are having directly in the lungs of patients.

In the lung, ILD has also been associated with higher levels of certain types of immune cells (alveolar macrophages). Normally, these immune cells are important in keeping the lungs free of pollutants and infection but in a large number of ILD cases, they can become ‘over-active’ and result in scarring. Developing treatments that target these immune cells could help to reverse or slow the rate of ILD progression.

Who can participate?
Adult patients with a diagnosis of suspected or confirmed ILD or bronchiectasis

What does the study involve?
This study involves a new compound that has been shown to dampen down the activity of these particular immune cells outside of the body. The next step is to find out if small amounts of this compound target these cells in the lung. This liquid compound will be delivered into the lung during a routine bronchoscopy procedure and small amounts of lung fluid or samples will be taken to assess if it is having an effect on the immune cells.

What are the possible benefits and risks of participating?
While there will be no direct benefit to the patient, we are testing this new compound to see if it has an effect on certain immune cells that are key to the progression of inflammation in the lung. The information we gain from this study will help us improve our understanding and treatment of inflammatory lung diseases.

Where is the study run from?
The Queen's Medical Research Institute, The University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
June 2022 to September 2024

Who is funding the study?
Adiso Therapeutics (USA)

Who is the main contact?
Dr Annya Bruce, annya.bruce@ed.ac.uk (UK)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
318427

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AC22119, IRAS 318427

Study information

Scientific Title
Micro: A phase 0 experimental medicine study to provide early mechanistic data in humans of NLRP3/1 inflammasome inhibition after direct intrapulmonary dosing of ADS032.

Acronym
MICRO

Study objectives
This study seeks to test the hypotheses that a novel clinical investigational agent (CIA) can attenuate alveolar macrophage (AM) inflammasome activity. This study specifically asks the question:
In treatment-naive patients with confirmed or suspected interstitial lung disease (ILD) (which includes sarcoidosis), and in patients with bronchiectasis, can this compound that is delivered to the distal lung, attenuate IL-1β secretion and other markers of inflammasome activity in AMs retrieved from bronchoalveolar lavage (BAL)?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/04/2023, South Central - Oxford B Research Ethics Committee (Temple Quay House, 2 The Square, Bristol , BS1 6PN, United Kingdom; +44 207 104 8241; oxfordb.rec@hra.nhs.uk), ref: 23/SC/0077

Study design
Exploratory non-randomized phase 0 experimental medicine study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Interstitial lung disease or bronchiectasis

Interventions
This study seeks to test the hypotheses that a novel Clinical Investigational Agent (CIA), ADS032, can attenuate alveolar macrophage inflammasome activity in the human lung. ADS032 will be microdosed into the distal lung during a bronchoscopy procedure. Up to 100 µg of ADS032 (approximately 1.5 ml) will be delivered into the distal lung using a medically approved catheter. This can be administered as single or smaller divided doses. Lung fluid samples and blood will be taken either before, during or after the procedure. Patients will be reviewed at 4 hours and their participation in the study will end at 24 hours post-procedure.

Group 1: Patients with suspected or confirmed Interstitial lung disease (ILD) or bronchiectasis will receive a microdose of the inflammasome inhibitor ADS032. Patients will also receive the equivalent regime of saline to enable them to act as their own control when samples are compared.
Group 2: Patients undergoing surgical resection of the lung will receive a microdose of ADS032.

Intervention Type
Drug

Phase
Phase 0

Drug/device/biological/vaccine name(s)
ADS032

Primary outcome(s)
To evaluate early mechanistic data following administration of ADS032 assessed by measuring key inflammatory cytokine levels in the lung fluid of suspected or confirmed ILD patient groups measured using a variety of laboratory techniques, for example, ELISA at a single time point post the bronchoscopy

Key secondary outcome(s))
1. Key exploratory biomarkers and their response will be evaluated (e.g. cytokines, chemokines, cell surface markers) will be measured using a variety of laboratory techniques immediately before the procedure and following the administration of ADS032 at a single time point post bronchoscopy
2. Pharmacokinetics parameters (e.g. quantification) of ADS0132 in blood and urine measured using standard laboratory techniques immediately before the procedure and 4 hours post procedure

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. Provision of informed consent
2. Aged at least 18 years old and over
3. Diagnosis of suspected or confirmed ILD or bronchiectasis (Group 1) and ability to have a bronchoscopy
4. Patient undergoing surgical resection of lung for a suspected inflammatory, fibrotic or malignant process (Group 2)
5. Is not participating in a Clinical Trial of an Investigational Medicinal Product (CTIMP)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding
2. Known hypersensitivity to ADS032
3. In the Investigator’s opinion, the patient is unwilling or unable to undergo a bronchoscopy, laboratory tests or other study procedures
4. ILD and bronchiectasis patients receiving steroids or other immunomodulators (defined as any drugs that may suppress the immune system - azathioprine, mycophenolate, ongoing chemotherapy, macrolide antibiotics)
5. Already participated in Group 1 of this study

Date of first enrolment
15/09/2023

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Sponsor information

Organisation
Accord (United Kingdom)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Industry

Funder Name
Adiso Therapeutics

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
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes