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Investigating the efficacy and tolerability of nintedanib therapy in idiopathic-inflammatory-myopathy-related interstitial lung disease

Submission date
24/07/2020

Recruitment status
No longer recruiting

Registration date
30/07/2020

Overall study status
Completed

Last Edited
24/05/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Interstitial lung disease (ILD) is a group of lung conditions that affects the network of tissue (interstitium) that supports the air sacs of the lungs. ILD can cause stiffness in the lungs and lead to shortness of breath and death.

Idiopathic inflammatory myopathy (IIM) is a group of autoimmune disorders that cause inflammation of the muscles used for movement and lead to progressive muscle weakness. IIM can also affect non-muscular areas and the lung interstitium is the ILD is the most common non-muscular area affected. It is reported that 78% of IIM patients will develop ILD.

Idiopathic-inflammatory-myopathy-related interstitial lung disease (IIM-ILD) is frequently aggressive and may not respond to conventional therapies including glucocorticoids and immunosuppressive drugs. Meanwhile, the rapid progression of interstitial lung disease (RP-ILD) is a major cause of death in IIM patients. It is therefore necessary to search for more successful treatment for IIM-ILD.

Nintedanib has been proven effective and relatively safe in idiopathic pulmonary fibrosis and systemic-sclerosis-associated interstitial lung disease, however, its efficacy and tolerability are not known in adult idiopathic-inflammatory-myopathy-related interstitial lung disease (IIM-ILD). This study aims to assess how effective and well-tolerated nintedanib is in patients with IIM-ILD.

Who can participate?
Adult patients who regularly attend the outpatient or inpatient department of the study center with a diagnosis of IIM-ILD.

What does the study involve?
Patients who agree to participate will receive nintedanib therapy (150 mg, twice daily by mouth) in addition to standard treatment. Those who do not agree will receive standard immunosuppressive medication only.

What are the possible benefits and risks of participating?
Patients who received the nintedanib therapy may benefit from a therapeutic effect of nintedanib of slowing the progress of interstitial lung disease, reducing the chance of rapid progression, and improved survival. However, participants might experience side effects such as diarrhea and hepatic (liver) insufficiency as a result of this medication.

Where is the study run from?
The First Affiliated Hospital, College of Medicine, Zhejiang University (China)

When is the study starting and how long is it expected to run for?
From December 2017 to April 2020

Who is funding the study?
The National Natural Science Foundation of China (81701602) and Natural Science Foundation of Zhejiang Province (LQ20H100003) (China)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title
A real-world analysis of Nintedanib therapy in Idiopathic-inflammatory-myopathy-related Interstitial Lung Disease (NIILD): an efficacy and tolerability pilot study

Acronym
NIILD

Study objectives
Nintedanib is efficient and relatively safe in adult idiopathic-inflammatory-myopathy-related interstitial lung disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/05/2020, the Research Ethics Committee of the First Affiliated Hospital of Zhejiang University (FAHZJU) (#79 Qingchun Road, Hangzhou, Zhejiang Province, P.R.China, 310003; +86 (0)571-87236629; zyiitlunli@163.com; kjkzyyy@163.com), ref: 2020-200, 2018-224

Study design
Single-center interventional non-randomized real-world analysis pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Interstitial lung disease in idiopathic inflammatory myopathy

Interventions
Participants who agree to participate will receive nintedanib (150 mg, twice daily, orally) in addition to traditional immunosuppressive therapy. Patients who do not agree to participate will only receive traditional immunosuprresive medications. The duration of treatment and follow-up should be at least 6 months.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Occurrence of rapid progression of interstitial lung disease (RP-ILD), measured by the number of participants meeting the criteria of RP-ILD, assessed at the end of the follow-up. Patients with RP-ILD are defined as those presenting with progressive dyspnea and progressive hypoxemia, a worsening of interstitial change on the chest radiograph within 1 month after the initial visit or onset of respiratory symptoms.

Secondary outcome measures
1. Time to death from any cause, measured through recording of survival or not and the length of follow-up, at the end of the follow-up. Cause of death will also be recorded in the follow-up such as exacerbation of interstitial lung disease, cardiopulmonary failure of unknown origin, pulmonary artery hypertension, etc.
2. Complications of pulmonary infection, measured and recorded in the process of follow-up, at the end of follow-up. Pulmonary infection will be identified based on International Statistical Classification of Diseases, 10th revision (ICD-10)-coded discharge diagnosis of community-acquired pneumonia (CAP), hospital-acquired pneumonia (HAP), pulmonary fungal infection or pulmonary infection. Responsible pathogens were recognized based on repeated cultures /smears of bronchoalveolar lavage fluid (BALF) or sputum before related treatment.
3. Difference in immunosuppressive regimen such as dose of steroid, whether the potent and expensive intravenous immunoglobulin was used, etc. measured and recorded in the process of follow-up, at the end of follow-up
4. Tolerability of nintedanib will be measured as the incidence of adverse events, the incidence of dose reduction, or discontinuation due to adverse events, at the end of follow-up

Overall study start date
01/12/2017

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Diagnosis of dermatomyositis, polymyositis or amyopathic dermatomyositis that meets the 2017 ACR/EULAR classification criteria
3. Attending a regular outpatient visit or hospitalization in the First Affiliated Hospital, College of Medicine, Zhejiang University

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
over 100

Total final enrolment
151

Key exclusion criteria
1. Overlap syndromes with other connective tissue diseases (CTDs)
2. Attending outpatient visit or hospitalization for reasons unrelated to myositis and its complications, such as fracture, pregnancy, acquired immunodeficiency syndrome, cataract, and etc.
3. Previous use of nintedanib, or previous/present use of pirfenidone
4. Loss to follow-up without death from any cause within 6 months after the initial outpatient visit or hospitalization

Date of first enrolment
01/01/2018

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
China

Study participating centre
First Affiliated Hospital Zhejiang University
Department of Rheumatology
79 Qingchun Road
Hangzhou
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Sponsor information

Organisation
National Natural Science Foundation of China

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Sponsor type
Government

Website
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ROR
https://ror.org/01h0zpd94

Organisation
Natural Science Foundation of Zhejiang Province

Sponsor details
Provincial Natural Science Foundation Office
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Sponsor type
Government

Website
http://www.zjnsf.gov.cn/

ROR
https://ror.org/05m1p5x56

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Natural Science Foundation of Zhejiang Province

Alternative Name(s)
Zhejiang Natural Science Foundation, , , Zhejiang Provincial Natural Science Foundation, Zhejiang Provincial Natural Science Fund, ZJNSF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/10/2020

Individual participant data (IPD) sharing plan

Data including therapy duration, doses, adverse events, age, and sex of patients receiving nintedanib therapy will be available as supplements of the future publication. Other parts of the data in this study will be provided upon request.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/02/2021	24/05/2021	Yes	No