Trial Description

Title

**Safety and clinical effectiveness of autologous mesenchymal stromal cell infusion as adjunct
treatment in patients with Idiopathic Pulmonary Fibrosis**

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Idiopathic pulmonary fibrosis (IPF) is a chronic disease characterized by a progressive decline in lung function and associated with a poor prognosis. A number of treatments have been investigated in the past for IPF but these are no longer considered effective treatment options. Many studies suggest the hypothesis that IPF is an inflammatory disorder with following fibrosis of lung tissue. The study motivation came from evidence that mesenchymal stromal cells (MSC) can repair damaged lung tissue, reduce inflammation and prevent fibrosis in the lungs. MSC will be extracted from IPF patients' bone marrow, cultured and re-infused to the patients. Safety and clinical effectiveness of MSC treatment will be assessed and compared with conventional treatment for IPF.

Brief Summary in Scientific Language

Idiopathic pulmonary fibrosis (IPF) is defined as a specific form of chronic, progressive fibrosing interstitial pneumonia of unknown cause, occurring primarily in older adults, and limited to the lungs. It is characterized by progressive worsening of dyspnea and lung function and is associated with a poor prognosis. A number of treatments have been investigated in the past for IPF, including interferon gamma-1β, bosentan, ambrisentan, and anticoagulants, but these are no longer considered effective treatment options. Many studies are based on the hypothesis that IPF is an inflammatory disorder. Some preclinical studies have shown that MSC can reduce inflammation-induced damage in the lungs, they also can prevent pulmonary fibrosis by decreasing expression of transforming growth factor β1. In this clinical trial patients with IPF will receive infusion of autologous bone marrow derived MSC. Safety and clinical effectiveness of MSC treatment will be assessed and compared with conventional treatment for IPF.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00008790**
- Date of Registration in DRKS: **2015/07/13**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EC-01 RRPCPTB , Ethic Committee of the Republican Research and Practical Centre for Pulmonology and TB, Minsk, Belarus**

Secondary IDs

Health condition or Problem studied

- ICD10: **J84.1 - Other interstitial pulmonary diseases with fibrosis**

Interventions/Observational Groups

- Arm 1: **Single infusion of autologous MSC will be given to patients with IPF in addition to conventional therapy. Conventional therapy can include: non-pharmacological (oxygen, if hypoxic; pulmonary rehabilitation); pharmacological (prescribed after specialists discussion in accordance with “An Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management” and based on patients’ individual values and preferences); treatment of comorbidities (pulmonary hypertension and gastroesophageal reflux) and symptoms control.**
- Arm 2: **Patients with IPF on conventional therapy. Conventional therapy can include: non-pharmacological (oxygen, if hypoxic; pulmonary rehabilitation); pharmacological (prescribed after specialists discussion in accordance with “An Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management” and based on patients’ individual values and preferences); treatment of comorbidities (pulmonary hypertension and gastroesophageal reflux) and symptoms control.**

Characteristics

- Study Type: **Interventional**

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- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **I-II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary end points are the following: the adverse events, the changes in vital capacity and DLCO between baseline and month 6, 12.

Secondary Outcome

Chest X-ray and CT scan at baseline, 6 and 12 months, and mortality during 12 months

Countries of recruitment

- BY **Belarus**

Locations of Recruitment

- University Medical Center **The Republican Research and Practical Centre for Pulmonology and TB, Minsk**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/08/31**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **21 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

Patients 21 through 75 years of age with diagnose of IPF based on diagnostic criteria of “An Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management”. The duration of the disease should be more than three months, bilateral predominantly basilar inspiratory crackles should be present. In addition, the following functional abnormalities should be present: dyspnea, vital capacity of no more than 80 percent of the predicted value, single-breath carbon monoxide diffusing capacity (DLCO) less than 80 percent of the predicted value.

Exclusion criteria

Any one of the criteria below makes the patient non-eligible for enrolment into the

study:

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*