

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation the clinical trial of Rituximab (Zytux) efficacy in improving the skin stiffness and lung involvements of the patients with diffuse cutaneous Systemic sclerosis with diffuse skin involvement

Protocol summary

Summary

Systemic sclerosis (SSc) is a chronic disease with increased skin and lung fibrosis. The treatments which are used have the limited effect on skin fibrosis. This disorder is a disabling disease which needs the new and effective treatments. Its pathogenesis is unknown, but it seems that B cells by antibody production, hypergammaglobulinemia and polyclonal hyperactivation has a significant role. In addition, CD19 expression is augmented in memory and naive B cells of SSc patient. The skin biopsy of the patients shows the CD20 positive cells infiltrate, consequently the B cells are targeted for treatment. Rituximab is a monoclonal antibody against CD20 which leads to decrease the peripheral B cells. Rituximab was used for other autoimmune disorders like systemic lupus erythematosus and vasculitis with limited side effects. Prescription of Rituximab for mouse model with skin stiffness leads to reducing the skin fibrosis. In addition the evidences are exist for graft versus host disease treatment. According to the results' of the investigations on SSc treatment, we have designed this study to evaluate the efficacy of Rituximab on skin fibrosis and lung involvement. The other results are listed below: In this study the Iranian biosimilar of Rituximab (Zytux) will be used; the efficacy of Rituximab was not evaluated previously on Iranian population; the results of the previous studies with the same subject were highly controversial; in addition to modified Rodnan skin score, the lung involvement and disease severity score will be also evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022126686N1**

Registration date: **2016-08-12, 1395/05/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-12, 1395/05/22

Registrant information

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Name of organization / entity

tehran university

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the clinical trial of Rituximab (Zytux) efficacy in improving the skin stiffness and lung involvements of

the patients with diffuse cutaneous Systemic sclerosis with diffuse skin involvement	clinical trial.
Public title Evaluation the efficacy of Rituximab (Zytux) in diffuse cutaneous Systemic sclerosis treatment	Secondary Ids empty
Purpose Treatment	Ethics committees
Inclusion/Exclusion criteria Inclusion Criteria: age more than 20 year old; patients with diffuse cutaneous Systemic sclerosis (SSc) with disease duration less than 7 years from the Raynaud's phenomenon; modified Rodnan skin score (mRSS) more than 20; the presence of interstitial lung disease (ILD) in high resolution computed tomography (HRCT) or pulmonary function test (PFT) or both (if the ILD involvement is more than 20% it will be sufficient and in the other situation the ILD should be proved by HRCT and PFT); the mRSS should be remained unchanged after 6 months of the treatment with Endoxan or Cellcept as the previous therapy. Exclusion Criteria: the previous history of Rituximab administration; the history of nervous system disorders like Multiple sclerosis; the history of viral hepatitis like Hepatitis B or C; the history of human immunodeficiency virus infection; the history of tuberculosis infection with PPD more than 5 millimeter; the history of malignancy; dyspnea at rest; the sign and symptoms of congestive heart failure at rest; the history of infectious diseases; the history of cardiac arrhythmia on electrocardiogram; the history of prednisolone usage more than 10 mg per day; tricuspid regurgitation jet flow velocity more than 2.8; pulmonary arterial pressure more than 35 according to trans-thoracic ecocardiography; ejection fraction less than 40%; diffusion capacity of the lung for carbon monoxide less than 50%; forced vital capacity less than 50%; serum creatinine level more than 1.5; the history of scleroderma renal crisis; the history of co-morbid cardiac, pulmonary and renal diseases unrelated to SSc.	1 Ethics committee Name of ethics committee Technology and research management center of Tehran University of Medical Sciences Street address Number 6, Keshavarz boulevard, Ghods avenue, the central department of Tehran University of Medical Sciences City Tehran Postal code Approval date 2015-12-21, 1394/09/30 Ethics committee reference number IR.TUMS.REC.1394.1454
Age No age limit	Health conditions studied
Gender Both	1 Description of health condition studied Systemic sclerosis (Scleroderma) ICD-10 code M34.8 ICD-10 code description systemic sclerosis with lung involvementJ99.1*
Phase 3	Primary outcomes
Groups that have been masked No information	1 Description Skin stiffness (modified Rodnan skin score) Timepoint Before and after 6 months of treatment Method of measurement The examination by fixed Rheumatologist
Sample size Target sample size: 20	2 Description Lung involvement according to ground glass opacities and lung fibrosis Timepoint Before and after 6 months of treatment Method of measurement Spirometry, diffusion capacity of the lungs for carbon monoxide, high resolution computed tomography
Randomization (investigator's opinion) N/A	Secondary outcomes
Randomization description	
Blinding (investigator's opinion) Not blinded	
Blinding description	
Placebo Not used	
Assignment Single	
Other design features This project is designed in clinical trial without randomization and blindness. It is a before and after	

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Description

The side effects of the biosimilar drug, Zytux

Timepoint

Three and six months after treatment if any side effect will present

Method of measurement

Clinical and laboratory examination and diagnosis

Intervention groups

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Description

The Zytux which is Rituximab biosimilar with the Iran insurance approval will be administered intravenously with the dosage of 1 gram on the beginning of the treatment, followed by an other 1 gram in two weeks in the hospital. Before the administration, 10 milliliter diphenhydramin and 100 milligram hydrocortisone will be administered to the patients. All of the administrating processes will be under the monitoring.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology research center, Rheumatology department of Shariati hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Aryogen pharmed

Full name of responsible person

Amir Farshchy

Street address

Number 140, corner of Tajbakhsh street, 24th kilometer KM Terhan-Karaj, Makhsoos road, Alborz, Iran

City

Karaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Aryogen pharmed

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Rheumatology research center

Full name of responsible person

Kourosh Sheikh Ahmadi

Position

Rheumatology fellowship

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty