Danazol for the Treatment of Pulmonary Fibrosis

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To study the efficacy of danazol in patients with pulmonary fibrosis, and to investigate what factors are associated with effective treatment.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON44571

Source
ToetsingOnline

Brief title
Danazol for pulmonary fibrosis

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Idiopathic Pulmonary Fibrosis; Pulmonary Fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds

Intervention

Keyword: Danazol, Idiopathic Pulmonary Fibrosis, Telomeres

Outcome measures

Primary outcome

The main study parameter is difference in yearly decline in lung function between the period prior to danazol treatment and the first year after start of danazol treatment.

Secondary outcome

Secondary outcome parameters are telomere length at baseline compared to that during danazol treatment, haematological parameters at baseline compared to during danazol treatment, survival, radiological qualification of pulmonary fibrosis at baseline compared to during danazol treatment, quality of life at baseline compared to that during danazol treatment, and adverse events during danazol treatment.

Study description

Background summary

Idiopathic pulmonary fibrosis is a severe lung disease, for which there are limited treatment options. Telomere shortening plays an important role in the pathogenesis of idiopathic pulmonary fibrosis. Danazol is a synthetic hormone with light androgenic effects that has been shown to lengthen telomeres in patients with telomere disease. At present, idiopathic pulmonary fibrosis patients at St. Antonius Hospital are offered off-label treatment with danazol when they have progressive disease despite other treatments. However, the use of danazol has not been studied extensively in pulmonary fibrosis patients. Furthermore, it is not known if danazol would be an effective therapy for all pulmonary fibrosis patients, or just for a subset of patients.

Study objective

To study the efficacy of danazol in patients with pulmonary fibrosis, and to investigate what factors are associated with effective treatment.

Study design

Observational drug study

Study burden and risks

Patients will receive danazol in the course of regular clinical care. Participating in this study is optional. Participation in the study will involve the drawing of extra blood samples at five regular control visits (at these visits the study requires the drawing of additional blood, next to blood required for regular tests; no extra line is required). Furthermore, study participants will have to fill in three questionnaires prior to starting treatment with danazol, as well as three-monthly during the first twelve months of danazol treatment. After the first year of danazol treatment, the study requires 6-monthly drawing of extra blood samples (in addition to regular samples; no extra line required), when patients are still taking danazol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Consensus (working) diagnosis of IPF
- Age >= 18
- Starting treatment with danazol at St. Antonius Hospital (danazol treatment is offered to patients in the course of regular clinical care when: [1] treatment with both pirfenidone and nintedanib has been given or is not possible; and [2] there is proven clinical (decline in forced vital capacity (FVC) of >5% of predicted) and radiological (worsening of high-resolution computed tomography (HRCT) picture) progression of the disease)

Exclusion criteria

- Concomitant (severe) disease that precludes the ability to participate in the study protocol, or is likely to result in death within 30 days:
- Inability to give informed consent
- Not eligible for danazol treatment (patients will not be eligible to receive danazol treatment in the course of regular clinical care in case of: [1] severe cardiac, hepatic or renal disease; [2] use of statins metabolized by CYP3A4 (simvastatin, atorvastatin, lovastatin); [3] androgen-dependent tumor (e.g. prostate carcinoma); [4] increased thromboembolic risk, and no adequate prophylactic measures taken; [5] genital neoplasia; [6] porphyria; [7] pregnancy, or of childbearing potential and unwilling to take adequate contraceptive measures during danazol treatment)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	27-08-2018
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	danazol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	04-04-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-004906-16-NL
CCMO	NL62034.100.17