kofam

Koordinationsstelle Forschung am Menschen

CASE STUDY

Rituximab-induced pulmonary function changes: a prospective cohort study

CATEGORISING

Kind
Research project involving living people

Type
Research project invovling people that does not count as a clinical trial

Subtype

BACKGROUND

This study investigated whether rituximab, a drug commonly prescribed to patients with rheumatoid arthritis or inflammatory myositis, was associated with subclinical interstitial lung disease. We measured surrogate markers (by spirometry) of interstitial lung disease before, during and after treatment with rituximab, in patients with rheumatoid arthritis or inflammatory myositis for whom a de novo rituximab treatment was indicated.

METHODS

Subjects aged ≥18 years with established diagnosis of rheumatoid arthritis or inflammatory myositis, for whom a de novo rituximab treatment was indicated, were evaluated by spirometry for surrogate markers of interstitial lung disease (forced vital capacity and diffusing capacity of the lung for carbon monoxide). We measured surrogate markers (by spirometry) immediately before initiation of rituximab therapy and 2, 4, 8 weeks and 6 months after initiation of rituximab therapy. We defined a reduction in forced vital capacity of ≥10% or a fall of ≥15% in diffusing capacity of the lung for carbon monoxide as indicative for subclinical interstitial lung disease. The primary outcome was the rate of interstitial lung disease 6 months after treatment with rituximab.

QUESTIONS OF THE CATEGORISER

Does the research project come under the scope of application of the Human Research Act?
Yes

BECAUSE
This project was based on a study protocol that defines the exact procedures to be used. The study included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Adults ("persons") whose diagnosis of rheumatoid arthritis or inflammatory myositis was established, and for whom current medical routine/practice/standard indicated a de novo rituximab treatment, were tested for lung function test with spirometry. The study sought to determine if rituximab treatment was associated with subclinical interstitial lung disease ("research concerning human diseases").

Is the research project a project involving living persons?
Yes

BECAUSE
This study included adults ("persons") with established diagnosis of rheumatoid arthritis or inflammatory myositis, for whom a de novo rituximab treatment was indicated.

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Is the research project a clinical trial as defined by ClinO or ClinO-MD?
No

BECAUSE
Spirometry was used to measure surrogate markers for interstitial lung disease in adults whose diagnosis of rheumatoid arthritis or inflammatory myositis was established, and for whom rituximab treatment was indicated. Participants received rituximab according to current medical practice. This study involved no health-related interventions. Spirometry was a study-related procedure ("diagnostic measure") that measured lung function, and was not used to investigate its effects on health or on the structure and function of the human body".

Does the research project involve measures that involve minimal risks and stress for the participating persons?
Yes

BECAUSE
Spirometry is a common test that measures body function. It is non-invasive test; patients blow into a tube. Spirometry poses minimal risk to patients.

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