

BEISPIELSTUDIE

Rituximab-induced pulmonary function changes: a prospective cohort study

KATEGORISIERUNG

Gattung

Forschungsprojekt mit lebenden Personen

Art

Nicht als klinischer Versuch geltendes Forschungsprojekt (i.d.R. Beobachtungsstudie)

Unterart

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 $\geq 10\%$ or a fall of $\geq 15\%$ 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.

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?

Ja

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").

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?

Ja

BECAUSE

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

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?

Nein

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".

Werden im Forschungsprojekt Massnahmen angewendet welche für die teilnehmenden Personen mit minimalen Risiken und Belastungen verbunden sind?

Ja

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.