

Study profiles side-effects linked to common immunosuppressant methotrexate

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New research led by University of Manchester and NIHR Manchester Biomedical Research Centre (BRC) scientists has profiled the side effects of methotrexate—a common drug used to treat arthritis and other

autoimmune diseases.

The authors hope their findings—published in the journal *Rheumatology*—will ease the concerns of patients before commencing [treatment](#), who often lack knowledge of the drug, its impact and side effects.

Though the study is unable to conclude if the drug causes the side effects they report in [arthritis](#) patients, the associations give them and their doctors—valuable information, argue the researchers.

The principle investigator, Dr. Suzanne Verstappen from The University of Manchester, is supported by Versus Arthritis and Manchester BRC. The BRC's Musculoskeletal (MSK) research theme aims to use biomarkers such as [patient data](#), to predict outcomes and personalize treatments for patients with MSK conditions.

The team evaluated data of 1,069 patients who participated in the Rheumatoid Arthritis Medication Study (RAMS) from 38 hospitals across the UK, including in Greater Manchester. The patients were recruited to the study before starting methotrexate treatment and were followed up for one year.

At six and 12-months, 957 patients (89.5 percent) and 902 patients (84.4 percent) were still taking the drug orally, respectively.

However, 106 (9.9 percent) and 169 (15.8 percent) had switched to subcutaneous methotrexate by six and 12 months respectively.

Side effects were common among patients over the first year of methotrexate, though most were not serious.

Overall, 77.5 percent experienced at least one side effect during the 12

months: 250 reported only one, 169 reported two, and the others reported three or more.

Of the side effects associated with taking the drug:

- 42 percent were gastrointestinal, including nausea (31 percent) and diarrhea (15 percent).
- 39.6 percent were generalized, including fatigue (29 percent).
- 28.6 percent were neurological, including headaches (19 percent) and dizziness (12 percent).
- 26.0 percent were mucocutaneous, including alopecia (9 percent), and mouth ulcers (12 percent).

Older age was associated with less reporting of gastrointestinal side effects, whereas women were more likely to report gastrointestinal, mucocutaneous, or neurological side effects compared to men.

Alcohol consumption at the start of treatment was associated with nausea, alopecia, and mucocutaneous side effects while taking the drug. Patients who had higher levels of concern about treatment reported more gastrointestinal side effects, particularly nausea.

PI of the RAMS study, Dr. Suzanne Verstappen is a Reader in musculoskeletal epidemiology at The University of Manchester and a researcher for Manchester BRC's Adult Inflammatory Arthritis research program. She says that "Methotrexate has transformed the treatment of inflammatory arthritis and improved the lives of almost two million people worldwide."

"But worrying about side effects could stop patients from initiating this important drug, or reduce adherence to treatment."

"These findings, however, provide patients and clinicians with insight

into the management of patients with rheumatoid arthritis starting methotrexate."

"Their concerns can be lessened by stressing the benefits of the treatment alongside a more specific discussion about side effects."

Ph.D. researcher Ahmad Sherbini and first author of the manuscript from The University of Manchester, said that "methotrexate is currently the drug of first choice for newly diagnosed patients with rheumatoid arthritis due to its low-cost and established efficacy."

"However, side effects associated with it have a considerable impact on treatment retention rates during the first year of treatment."

"Using the data in this study, patients can make informed decisions whether to start this [drug](#) and potentially increasing adherence to treatment."

"It can also help identifying patients with higher risk of side effects who require frequent monitoring and additional GP visits. Ultimately and with further studies, treatment can be tailored to patients, and better resource utilization can be achieved."

Dr. Natalie Carter, Head of Research Engagement at Versus Arthritis says that "methotrexate can be a highly effective treatment in controlling inflammatory arthritis, but for many there can be sides effects and illness which causes worry and distress."

"Research like this is vitally important. It means that people with arthritis are better informed on the medications being suggested and can support them when navigating a sometimes confusing and complicated treatment regime, especially when first diagnosed."

"With a better understanding on the types of [side effects](#) caused by medication people with arthritis can have productive conversations with their rheumatology team about their treatments on what is working, what is not, and how they can tailor that treatment to get the best possible result in managing their condition."

More information: Ahmad A Sherbini et al, Rates and predictors of methotrexate-related adverse events in patients with early rheumatoid arthritis: results from a nationwide UK study, *Rheumatology* (2022). doi.org/10.1093/rheumatology/keab917

Provided by University of Manchester

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