Effect of Corticosteroid-Sparing Treatment With Mycophenolate Mofetil vs Methotrexate on Inflammation in Patients With Uveitis
A Randomized Clinical Trial

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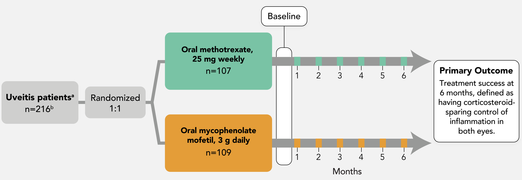
Methotrexate and mycophenolate mofetil are commonly used immunomodulatory therapies for achieving corticosteroid-sparing control of noninfectious uveitis, but there is uncertainty about which drug is more effective. The objective of this randomized clinical trial is to examine whether methotrexate or mycophenolate is more effective as first-line immunosuppressive treatment for patients with noninfectious intermediate uveitis, posterior uveitis, and panuveitis.

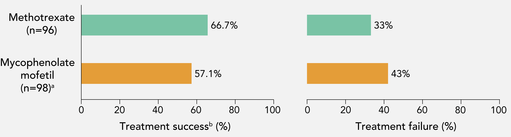
The First-line Antimetabolites as Steroid-sparing Treatment (FAST) uveitis trial was a National Eye Institute-supported multicenter, randomized, parallel, observer-masked clinical trial.



[a] 265 adults with noninfectious uveitis requiring corticosteroid-sparing immunosuppressive therapy from 9 referral eye centers in India, the United States, Australia, Saudi Arabia, and Mexico were screened between August 22, 2013, and August 16, 2017.
[b] 49 patients were excluded from the 265 screened.

The methotrexate treatment group had a higher treatment success rate compared to the mycophenolate mofetil treatment group.

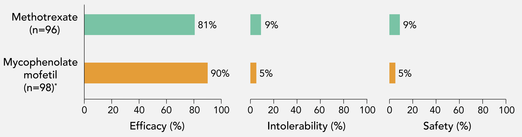
Primary analysis of patient-level characteristics comparing 6-month results of methotrexate and mycophenolate mofetil for noninfectious uveitis



[a] Mycophenolate mofetil is the reference group.
[b] Treatment success was defined by achieving corticosteroid-sparing control of inflammation in both eyes at the month 6 visit.

Efficacy was the main reason for treatment failure in both methotrexate and mycophenolate mofetil groups.

Reason for treatment failure comparing 6-month results of methotrexate and mycophenolate mofetil for noninfectious uveitis

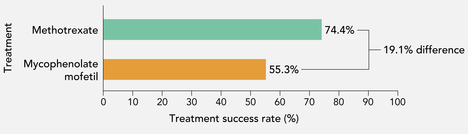


*Mycophenolate mofetil is the reference group.

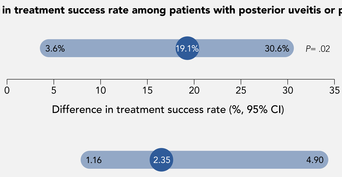
- Treatment failure due to efficacy was defined by not achieving treatment success at month 6 or could be declared earlier if patient had persistent worsening inflammation.
- Treatment failure due to intolerability was declared if a patient was unable or unwilling to continue medication due to adverse effects.
- Treatment failure due to safety was declared if a patient had an abnormal laboratory result that qualified as a serious adverse event.

Methotrexate was found to be more effective in patients with posterior uveitis or panuveitis, with a 19.1% difference in treatment success rate between the two treatment groups.

Treatment success comparison among patients with posterior uveitis or panuveitis



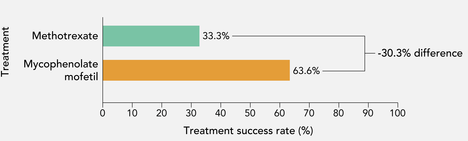
Difference in treatment success rate among patients with posterior uveitis or panuveitis



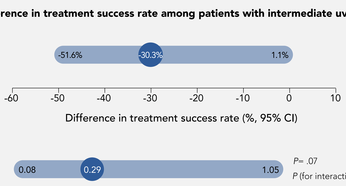
CI = Confidence interval.

Although the results favored mycophenolate mofetil among patients with intermediate uveitis, no significant difference was found in treatment success.

Treatment success comparison among patients with intermediate uveitis

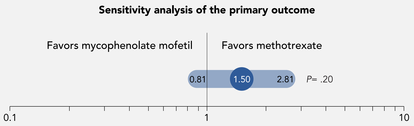


Difference in treatment success rate among patients with intermediate uveitis



Mycophenolate mofetil was not superior to methotrexate in control of inflammation of noninfectious uveitis.

Sensitivity analysis of the primary outcome



Conclusions

Among adults with noninfectious uveitis, mycophenolate mofetil was not more effective than methotrexate as first-line corticosteroid-sparing treatment and did not result in superior control of inflammation. Further research is needed to determine if either drug is more effective based on the anatomical subtype of uveitis.