Comparison of Gene-expression Modification Profiles Between Targeting IL-6 and Targeting JAK Treatment: Effecting Common Biological Processes or Disparate?

Y. Koyama, K. Numata, S. Nakamura, S. Nagano, T. Ota, T. Higuchi

Methods


N=15 TDF

N=10 TCZ

Peripheral blood drawn at baseline

Peripheral blood drawn 3 months after treatment

Compare Gene Expression
Tofacitinib, An Oral Janus Kinase Inhibitor, for the Treatment of Rheumatoid Arthritis: Safety and Efficacy in Open-label, Long-term Extension Up to 6 Years


Results

- N=4858 patients treated
- Total tofacitinib exposure: 12,359 patient-years
- Most common classes of adverse events (AEs):
  - Infections/Infestations: 63.4%
  - Musculoskeletal/connective tissue disorders: 33.9%
  - GI disorders: 29.9%
- SAEs occurred in 23% of patients
- Malignancies reported in 2.5%
- ACR response rates for tofacitinib were sustained to Month 72:
  - ACR 20: 80.8%
  - ACR 50: 61.5%
  - ACR 70: 35.9%

ACR: American College of Rheumatology

On Drug and Drug-free Remission by Baseline Disease Duration in the AVERT Trial: Abatacept Versus Methotrexate Comparison in Patients with Early Rheumatoid Arthritis

Methods

**Objectives:** To assess clinical outcomes in patients with early RA and ≤3 months disease duration compared with patients with >3 to ≤6 or >6 months disease duration after treatment with SC ABA+MTX or MTX alone, using data from AVERT.

**Patients with RA**
- Early active RA
- Anti-CCP-2 (+)

**SC Abatacept 125 mg/week**

**MTX alone**

Treated for 12 months.

All RA treatment was removed after 12 months in patients with DAS28 (CRP) <3.2

ABA: Abatacept, MTX: Methotrexate, SC: Subcutaneous


Results

Proportion of Patients with DAS28 (CRP) <2.6 Remission over Time by Disease Duration

<table>
<thead>
<tr>
<th>Withdrawal period</th>
<th>MTX ≤3 months (n=48)</th>
<th>MTX &gt;3 to ≤6 months (n=29)</th>
<th>MTX &gt;6 months (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTX alone</td>
<td></td>
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</tbody>
</table>

ABA: Abatacept, MTX: Methotrexate


First-in-patient Study of Namilumab, an Anti-GM-CSF Monoclonal Antibody, in Active Rheumatoid Arthritis: Results of the PRIORA Phase Ib Study

T. W. J. Huizinga, A. Batalov, K. Yablanski, R. Stoilov, E. Lloyd, T. Wagner, D. Saurinyy, B. Souberbielle, E. Esfandiari
Methods

- **Design**
  - Double-blind, placebo-controlled, randomized, dose-escalating Phase Ib study

- **Population**
  - Patients with mild-to-moderate RA on stable MTX doses for at least 12 weeks prior to randomization

- **Intervention**
  - Patients received a total of 3 single injections of namilumab 150 or 300 mg or matching placebo on Days 0, 15, and 29, with a 12-week follow-up

MTX: Methotrexate, RA: Rheumatoid Arthritis


Effects of Concomitant Methotrexate on the Long-term Outcome of Knee-joint Destruction in Patients with Rheumatoid Arthritis Treated with TNF Inhibitors


Results

[Graph and table showing data]

Effectiveness of Retreatment After Relapse of Rheumatoid Arthritis Patients Under Down-titrated Biological Therapy


Results

- N=256 biologic treated patients with RA
- n= 91 patients down-titrated
  - 52% were in remission
  - 24% with low disease activity
  - 24% with moderate disease activity
- Most patients (78.6%) were receiving their first biologic therapy

- Relapses (n=28)
  - Retreatment:
    - At full dose: 61%
    - At previous dose: 39%
  - 75% achieved EULAR good or moderate response within 6 months of retreatment
    - Did not differ on baseline disease activity or specific biologic agent

Discontinuation of Biologic DMARDs Increases the Risk of Sepsis and Mortality After Serious Infection

A. Richter, A. Strangfeld, M. Schneider, T. Klopsch, A. Kapelle, J. Kaufmann, A. Zink, J. Listing

Results

• Crude odds ratio (OR) of developing sepsis was 0.6 (CI: 0.3, 0.9)
  – bDMARD exposed versus bDMARD naïve
• 63% treated with csDMARDs at serious infection (SI) had discontinued bDMARDs prior to SI
  – Risk of sepsis increased 2 fold compared to continuous bDMARD exposure
  • OR: 2.0, CI: 1.3, 3.0


Results

<table>
<thead>
<tr>
<th></th>
<th>Sepsis after SI</th>
<th>Death after SI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
</tr>
<tr>
<td>Age at SI (by 10 years)</td>
<td>1.44</td>
<td>1.17; 1.77</td>
</tr>
<tr>
<td>Sex (males vs. females)</td>
<td>3.00</td>
<td>1.46; 5.77</td>
</tr>
<tr>
<td>Physical function (By 10% improvement)</td>
<td>0.91</td>
<td>0.84; 0.99</td>
</tr>
<tr>
<td>GC (0.3 mg/dL reference)</td>
<td>3.31</td>
<td>0.86; 2.03</td>
</tr>
<tr>
<td>GC (0.3 mg/dL upper 30%)</td>
<td>3.66</td>
<td>0.83; 2.06</td>
</tr>
<tr>
<td>TNF (yes vs. no)</td>
<td>0.55</td>
<td>0.36; 0.83</td>
</tr>
<tr>
<td>Other S01DRA (yes vs. no)</td>
<td>0.42</td>
<td>0.23; 0.76</td>
</tr>
<tr>
<td>Heart failure (yes vs. no)</td>
<td>0.59</td>
<td>0.26; 2.93</td>
</tr>
<tr>
<td>Hypertension (yes vs. no)</td>
<td>0.92</td>
<td>0.61; 1.42</td>
</tr>
<tr>
<td>Chronic renal disease (yes vs. no)</td>
<td>3.92</td>
<td>1.15; 12.07</td>
</tr>
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Multinomial regression for the risk of sepsis and death after serious infection

Results remained consistent in sensitivity analyses