Background: Fasting can improve clinical disease activity in rheumatoid arthritis (RA) [1], but mechanism involved are not clear. Recently, we demonstrated that monocytes in RA express transcriptome patterns of increased myelopoiesis, premature egress from bone marrow and prolonged circulation time as indicators of mature egress from bone marrow and reduced circulation time as indicators of inflammatory disease activity [2].

Objectives: This is an interim analysis from a multicenter, 2-part study evaluating the efficacy and appropriate duration of RCI therapy in patients with persistently active RA despite receiving 1–2 DMARDs and corticosteroids.

Methods: The study includes a 12-week open-label treatment period followed by a 12-week double-blind randomized maintenance phase for patients who achieve low disease activity (LDA) at Week 12. The secondary endpoints were proportion of patients that maintained LDA from Week 12 to Week 24, time to disease activity flare, safety, and tolerability. Disease activity was also assessed by the proportion of patients that achieved improvements in American College of Rheumatology (ACR)20, ACR50, and ACR70 scores at Week 12.

Results: As of December 18, 2017, 45 patients had completed the 12-week open-label treatment period of the study, and 12 patients had discontinued; 77.8% were female, with a mean age of 57 years. Patient baseline characteristics and the results of the primary and select secondary endpoints are presented in Table 1. Demonstrating that RCI altered the majority of patients with RA to achieve LDA at Week 12. To date, 21 adverse events (AEs) and 1 serious AE (chest pain) have been reported. The most common AEs were headache (3), urinary tract infection (2), and fall (2).

Table 1. Patient Baseline and Endpoint Results at Week 12

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAS28-ESR Score, mean</td>
<td>6.5</td>
<td>3.6</td>
</tr>
<tr>
<td>Tender Joint Count, mean</td>
<td>16.4</td>
<td>3.5</td>
</tr>
<tr>
<td>Swollen Joint Count, mean</td>
<td>12.5</td>
<td>3.2</td>
</tr>
<tr>
<td>LDA (DAS28-ESR &lt;3.2)</td>
<td>55.6%</td>
<td>84.4%</td>
</tr>
<tr>
<td>ACR50</td>
<td>57.8%</td>
<td></td>
</tr>
<tr>
<td>ACR70</td>
<td></td>
<td>35.6%</td>
</tr>
</tbody>
</table>

Conclusions: Intermittent fasting as a safe and effective treatment alternative to improve multiple measures of disease activity in patients with persistently active RA despite therapy with DMARDs and corticosteroids.

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Background: The study includes a 12-week open-label treatment period followed by a 12-week double-blind randomized maintenance phase for patients who achieve low disease activity (LDA) at Week 12. The secondary endpoints were proportion of patients that maintained LDA from Week 12 to Week 24, time to disease activity flare, safety, and tolerability. Disease activity was also assessed by the proportion of patients that achieved improvements in American College of Rheumatology (ACR)20, ACR50, and ACR70 scores at Week 12.

Results: As of December 18, 2017, 45 patients had completed the 12-week open-label treatment period of the study, and 12 patients had discontinued; 77.8% were female, with a mean age of 57 years. The finding that GC use was not associated with higher AE rates was unexpected and of interest.

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naive T-, B-cells and CD16 NK-cells along with a relative increase in memory lymphocytes and CD16+ NK-cells. These effects were also observed but less pronounced in controls.

Conclusions: Bowel cleanse and fasting in RA induces a reduction of inflammation related to monocyte activation and turnover immediately within few days. Changes in the monocyte compartment were specific for RA compared to controls and dominated the immunological changes, suggesting that innate triggering mechanisms from gut and its microbiota are etiologically relevant in RA.

REFERENCES:

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Disclosure of Interest: None declared


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Background: Intra-articular glucocorticoid (IAGC) injection treatment is an easy and effective way to treat signs and symptoms of arthritis and it has been used for decades. Serious adverse reactions are rare, but IAGC therapy has impact on endocrine balances. There is limited knowledge of the adequate dosing for different joints and dosing traditions vary all over world.

Objectives: To compare the relapse rate during 6 months after IAGC for knee synovitis, between two common doses (20 mg vs 40 mg) of triamcinolone hexacetonide (THA).

Methods: A total of 159 adult patients with rheumatoid arthritis (RA) or psoriatic arthritis (PsA) and active knee synovitis were randomized to IAGC injection with either 20 mg or 40 mg THA blinded to the participants. The primary endpoint was relapse of arthritis. When symptoms from the treated joint recurred and signs of arthritis could be confirmed on a following clinical examination a relapse was recorded and days from injection to relapse was calculated. At the end of the observation period those without relapse had a phone call to verify persistence of good treatment response.

Results: In this material there was no significant difference in patient characteristics at baseline and the proportion of relapse after 6 months were equal in the treatment arms (30% versus 32%, p=0.822). Additionally no significant differences were found in the subgroups with RA and PsA patients.

Conclusions: To reduce the risk for endocrine side effects and as no difference in treatment outcome between the compared doses was found the lower 20 mg THA dose should be preferred in IAGC treatment for knee synovitis in chronic polyarthritis.

Disclosure of Interest: None declared


SAT0251

SELECTIVE GLUCOCORTICOID RECEPTOR MODULATOR SHOWS POTENT ANTI-INFLAMMATORY EFFECT WITH IMPROVED METABOLIC PROFILE IN A PHASE I STUDY SUPPORTED BY IN VITRO DATA

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Background: Tofacitinib is an oral Janus kinase inhibitor for the treatment of rheumatoid arthritis (RA). ORAL Strategy (NCT02187055), a 12-month, global, Phase 2b/4 study, demonstrated that in patients with RA and an inadequate response to metotrextate (MTX), tofacitinib + MTX was non-inferior to adalimumab + MTX, while tofacitinib monotherapy was not non-inferior to either combination based on American College of Rheumatology (ACR)50 response rates at Month 6.

Objectives: To assess clinical and functional efficacy across treatments in the ORAL strategy trial using cumulative probabilistic methods.

Methods: Efficacy was evaluated between patients who received tofacitinib 5 mg twice daily (BID) as monotherapy (N=384), tofacitinib 5 mg BID + MTX (N=376) and adalimumab 40 mg subcutaneously once every 2 weeks + MTX (N=386) based on ACR responses and changes from baseline in Health Assessment Questionnaire-Disability Index (<3HA-DI) score at Month 12. Cumulative probability plots for ACR-n (where ACR is the % improvement from baseline in ACR components, and n represents the minimum % achieved by each patient)