Previewing at Level 1

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Still's disease: can recent advances in our understanding of its pathogenesis lead to targeted therapy?, *Nat Clin Pract Rheumatol*, 3(6), 2007, p. 328-35
State: Excluded, Level: 1

Keywords:
Adrenal Cortex Hormones/therapeutic use

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Abstract
Adult-onset Still's disease is a rare systemic inflammatory disease of unknown etiology, characterized by daily high, spiking fevers, evanescent rash, and arthritis. There is no single diagnostic test for adult-onset Still's disease; rather, the diagnosis is based on clinical criteria and necessitates the exclusion of infections, neoplastic, and other 'autoimmune' diseases. Proinflammatory cytokines such as interleukin (IL)-1, IL-6, and IL-18, interferon-gamma, tumor necrosis factor, and macrophage colony-stimulating factor are elevated in patients with adult-onset Still's disease and are thought to have a major role in the pathogenesis of the disease. Treatment consists of nonsteroidal anti-inflammatory drugs, corticosteroids, immunosuppressants (methotrexate, gold, azathioprine, leflunomide, cyclosporin, and cyclophosphamide), intravenous immunoglobulin, and cytokine (tumor necrosis factor, IL-1 and IL-6) inhibitors. Recent advances in basic immunology have enhanced our ability to under the pathogenic mechanisms associated with adult-onset Still's disease and have led to a paradigm shift where targeted treatments have an increasingly important role.

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1. Original research (no review articles, editorials, letters to the editor) published in English after 1990 in adult patients with rheumatoid or psoriatic arthritis AND is not a case report or case series?

- ○ Yes
- ○ No
- ○ Cannot determine
- ○ No, but article will be used for background

Clear Selection

2. Study includes one or more of the following pharmaceutical interventions (check all that apply):

- ☐ Corticosteroids
- ☐ Oral DMARDs including methotrexate, leflunomide, sulfasalazine, cyclosporine, hydroxychloroquine
- ☐ Biologic DMARDs including anakinra, etanercept, infliximab, adalimumab, abatacept, certolizumab, golimumab, tocilizumab, rituximab
- ☐ Cannot determine
- ☐ Comparison is not of interest

3. Study compares-

- ○ Two of the included drugs
- ○ Biological DMARD (TNF) versus placebo
- ○ One of the included drugs versus placebo but is of interest because of specific outcome such as adverse events
- ○ Nothing of interest and article should not be included
- ○ Cannot determine

Clear Selection

4. Addresses one or more of the following key questions (check all that apply):

- ☐ KQ1 For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce patient-reported symptoms, to slow or limit progression of radiographic joint damage, or to maintain remission (reduce the incidence flare-ups)?
- ☐ KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capacity or quality of life?
- ☐ KQ3 For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adverse effects?
- ☐ KQ4 What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups of patients based on stage of disease, history of prior therapy, demographics, concomitant therapies, or comorbidities?
- ☐ Cannot determine by the title or abstract
- ☐ None of the above

5. Study design is one of the following:

- ☐ RCT 3 months or longer

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Previewing at Level 2

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Stills disease: can recent advances in our understanding of its pathogenesis lead to targeted therapy?, *Nat Clin Pract Rheumatol*, 3(6), 2007, p. 328-35
State: Excluded, Level: 1

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1. Should the article be *excluded* for any of the following reasons?

- [ ] Study reported only in abstract
- [ ] Wrong outcome (i.e. pharmakinetic or intermediate outcomes)
- [ ] Wrong drug (not one of the following: corticosteroids, methotrexate, leflunomide, sulfasalazine, cyclosporine, hydroxychloroquine, anakinra, etanercept, infliximab, adalimumab, abatacept, certolizumab, golimumab, tocilizumab, rituximab)
- [ ] Wrong population (For example pediatric studies)
- [ ] Wrong publication type (e.g. letter or editorial)
- [ ] Wrong design (i.e. non-systematic meta-analysis or no comparison arm)
- [ ] RCT (n<100)
- [ ] Other? (Please explain!)
- [ ] Background article
- [ ] None of the above - should be included!

If the article has been excluded in the above question, the next two questions do not need to be answered.

2. Which of the following key questions are addressed by the article

- [ ] KQ1- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce patient-reported symptoms, to slow or limit progression of radiographic joint damage, or to maintain remission (reduce the incidence flare-ups)?
- [ ] KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capacity or quality of life?
- [ ] KQ3- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adverse effects?
- [ ] KQ4- What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups of patients based on stage of disease, history of prior therapy, demographics, concomitant therapies, or comorbidities?
- [ ] None of the above

3. What is the study design?

- ( ) RCT > or equal to 100
- ( ) Observational > or equal to 100
- ( ) Meta-analysis or systematic review (i.e. Cochrane Review)

○ None of the above, but it should be abstracted- please note why in the box!  

○ None of the above, so exclude.

Clear Selection

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Previewing at Level 3

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Stills disease: can recent advances in our understa
State: Excluded, Level: 1

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1. Author, Year, Study name if applicable (i.e. BeST):

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2. Country and setting:

If more than a couple of countries are included just call it multinational. Settings include primary care, hospitals, uni

3. Source of funding

- [ ] Pharmaceutical company or other commercial source - please list name.
- [ ] Government or non-profit organization - please list name.
- [ ] Not reported

4. Condition being treated:

- [ ] Rheumatoid arthritis
- [ ] Psoriatic arthritis
- [ ] Other? Please explain

5. STUDY DESIGN

- ( ) Controlled Trials
- ( ) Observational

Clear Selection

6.
What is being compared?

- [ ] 1 Oral DMARD vs 1 Oral DMARD
- [ ] 1 Oral DMARD vs 1 BIOLOGIC
- [ ] 1 Oral DMARD vs 1 Corticosteroid
- [ ] 1 BIOLOGIC vs 1 BIOLOGIC
- [ ] 1 BIOLOGIC vs 1 Corticosteroid

- [ ] 1 BIOLOGIC vs Placebo
- [ ] Combination therapy vs Combination therapy
- [ ] SINGLE DRUG vs Combination therapy
- [ ] Strategy (Describe the strategy in detail for each arm in the 'Other' text box for numbers 8-12)

7. How many comparison arms does this study have?

- ( ) 2 ARMS
- ( ) 3 ARMS
- ( ) 4 ARMS
- ( ) 5 ARMS

Clear Selection

8. Check off the drug(s) studied for **ARM 1** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

9. Check off the drug(s) studied for **ARM 2** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone

- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

10. Check off the drug(s) studied for **ARM 3** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab

- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

11. Check off the drug(s) studied for **ARM 4** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

12. Check off the drug(s) studied for **ARM 5** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine

- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

13. Research objective (*Please be brief and concise*):

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14. Overall study n =

Enlarge Shrink

15. Duration of study:

Enlarge Shrink

16. Inclusion criteria (check all that apply and list additional criteria in the text box)

- [ ] MTX Naive
- [ ] Early RA
- [ ] Treatment resistant

Additional inclusion criteria

17.

Exclusion criteria

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POPULATION CHARACTERISTICS

	ARM 1	ARM 2	
18. **Intervention/Treatment**			
19. # in group (n):			
20. Age (mean):			
21. Sex, female (%):			
22. Race, white (%):			
23. Race, black (%):			
24. Ethnicity, Latino (%):			
25. Disease duration (mean & SD):			
26. DMARD use (%):			
27. Corticosteroid use (%):			
28. MTX naive (%):			
29. Treatment resistant (%):			
30. Patients with early RA, three years or less, (%):			
31. Baseline DAS score:			
32. Tender joint count:			
33. Swollen joint count:			
34. Required treatment for latent TB:			
35. Other population characteristics?			

RESULTS: Outcome Measures and Health Outcomes
(Enter results for all time points and please specify units for all results)

	ARM 1	ARM 2	
36. ACR 20, %, (CI/SD/P value):			
37. ACR 50, %, (CI/SD/P value):			
38. ACR 70, %, (CI/SD/P value):			
39. PASI 20, %, (CI/SD/P value):			

40. PASI 50, %, (CI/SD/P value):

41. PASI 70, %, (CI/SD/P value):

42. HAQ, mean difference/absolute difference (CI/SD/P Value):

43. DAS, mean difference/absolute difference (CI/SD/P Value):

44. SF-36, mean difference/absolute difference (CI/SD/P Value):

45. PsARC, mean difference/absolute difference (CI/SD/P Value):

46. Radiographic measures, mean difference/absolute difference (CI/SD/P Value):

47. Quality of life scales (please name), mean difference/absolute difference (CI/SD/P Value):

48. Others, (please name); mean difference/absolute difference (CI/SD/P Value):

ATTRITION AND ADHERENCE

	ARM 1	ARM 2	
49. Overall attrition/withdrawal (n):			
50. Withdrawals due to adverse events (n):			
51. Withdrawals due to lack of efficacy (n):			
52. Adherent/compliant (n):			

53. Other attrition related comments?

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RESULTS: Adverse Events, n

	ARM 1	ARM 2	
54. Overall adverse events reported (n):			
55. Death (n):			
56. Lymphoma or leukemia (n):			
57. Skin cancer (basal cell or squamous cell) (n):			
58. Other cancer (specify) (n):			
59. Cardiovascular events (specify) (n):			
60. Hepatotoxicity/elevated liver enzymes (n):			
61. Tuberculosis (n):			
62. Pneumonia (n):			
63. Upper respiratory infection (n):			
64. Urinary tract infection (n):			
65. Other infections (specify) (n):			
66. Fractures (n):			
67. Infusion/injection site reactions (n):			
68. Skin rash (n):			
69. Demyelenation or multiple sclerosis (n):			
70. Progressive multifocal leukoencephalopathy (n):			
71. **Headache** (n):			
72. **Dizziness** (n):			
73. **Nausea or vomiting** (n):			
74. **Abdominal pain** (n):			
75. GI bleed or ulcer (n):			
76. Bowel obstruction (n):			
77. Other GI symptoms (specify) (n):			
78. Other AEs 1 (n):			
79. Other AEs 2 (n):			
80. Other AEs 3 (n):			

81. Other AEs 4 (n):

82. Any other AEs:

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83. Which Key Question(s) does this study address (check all that apply)?

- [ ] KQ1- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce disease activity, t
- [ ] KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capac
- [ ] KQ3- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adver
- [ ] KQ4- What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups

Quality Review for Controlled Trials

84. Randomization adequate?

- ○ Yes
- ○ No
- ○ Not randomized
- ○ Method not reported

Clear Selection

85. Allocation concealment adequate?

- ○ Yes
- ○ No
- ○ Not randomized
- ○ Method not reported

Clear Selection

86. Groups similar at baseline?

- ○ Yes
- ○ No (what are the differences)
- ○ Not reported
- ○ Not applicable

Clear Selection

87. Outcome assessors blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

88. Care provider blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

89. Patient blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

90. Overall attrition high (≥ 20%)?

- ○ Yes (please state how high) [ ]
- ○ No

Clear Selection

91. Differential attrition high (≥ 15%)?

- ○ Yes (please state difference) [ ]
- ○ No

Clear Selection

92. Were the outcome measures valid and reliable?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

93. Were the outcome measures equally applied?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

94. Was the statistical analysis based on intention-to-treat (ITT)?

- ○ Yes
- ○ No
- ○ Cannot tell
- ○ Not applicable

Clear Selection

95. Were there any post-randomization exclusions?

- ○ Yes (how many?) [ ]
- ○ No
- ○ Cannot tell

Clear Selection

96. Quality rating for efficacy/effectiveness

- ☐ Good
- ☐ Fair
- ☐ Poor

If poor, why? [ ]

Quality Review for Observational Studies

97. Were both groups selected from the same source population?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

98. Did both groups have the same risk of having the outcome of interest at baseline?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

99. Were subjects in both groups recruited over the same time period?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

100. Were measurement methods adequate and equally applied to both groups?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

101. Was an attempt made to blind the outcome assessors?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

102. Was the time of follow-up equal in both groups?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

103. Overall attrition high (≥ 20%)?

- ○ Yes (please state how high) [ ]
- ○ No

Clear Selection

104. Differential attrition high (≥ 15%)?

- ○ Yes (please state difference) [ ]
- ○ No

Clear Selection

105. Was confounding accounted for either through study design or statistical analysis?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

106. Did the statistical analysis adjust for different lengths of follow-up?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

107. Was the length of follow-up adequate to assess the outcome of interest?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

108. Quality rating for observational studies

- ☐ Good
- ☐ Fair
- ☐ Poor

Why?

109. Any other quality related comments?

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Quality Review for Adverse Events

110. Methods of adverse effects assessment

- ☐ Patient reported
- ☐ Physical exam at study visits
- ☐ Lab evaluations
- ☐ Standardized scale (e.g. WHO, UKU-SES)
- ☐ other (please specify)

111. Adverse events pre-specified and defined?

- ○ Yes
- ○ No

Clear Selection

112. Measurement techniques non-biased and adequately described?

- ○ Yes
- ○ No

Clear Selection

113. Quality rating adverse events assessment:

- ○ Good
- ○ Fair
- ○ Poor

Clear Selection

114. First abstraction done by:

- ○ Karen Crotty
- ○ Katrina Donahue
- ○ Rick Hansen
- ○ Dan Jonas
- ○ Linda Lux
- ○ Robert Rowbey
- ○ Rachael Schleiman
- ○ Other (please write your name in the adjacent box):

Clear Selection

115. Second abstraction done by:

- ○ Karen Crotty
- ○ Katrina Donahue
- ○ Rick Hansen
- ○ Dan Jonas
- ○ Linda Lux
- ○ Robert Rowbey
- ○ Rachael Schleiman
- ○ Other (please write your name in the adjacent box):

Clear Selection

116. Study is already included in systematic review/meta-analysis and does not need to be put in an evidence table

- ○ Yes
- ○ No

Clear Selection

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