### Table 1

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>All patients (n=22196)</th>
<th>csDMARD + TNFi (n=2547)</th>
<th>csDMARD + TNFi (n=9693)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>42.6 (12.5)</td>
<td>43.4 (12.0)</td>
<td>42.8 (12.2)</td>
</tr>
<tr>
<td>Females, %</td>
<td>41.1</td>
<td>37.3</td>
<td>38.2</td>
</tr>
<tr>
<td>Disease duration (yrs), mean (SD)</td>
<td>6.7 (8.0)</td>
<td>6.2 (7.7)</td>
<td>6.7 (7.4)</td>
</tr>
<tr>
<td>Enthesitis, %</td>
<td>50.3</td>
<td>16.7</td>
<td>33.9</td>
</tr>
<tr>
<td>SJC-28, median (IQR)</td>
<td>10 (0-1)</td>
<td>0 (0-0)</td>
<td>0 (0-0)</td>
</tr>
<tr>
<td>CRP (mg/L), median (IQR)</td>
<td>8 (2-20)</td>
<td>7.8 (2-20)</td>
<td>18 (6.7-32.6)</td>
</tr>
<tr>
<td>ASDAS, mean (SD)</td>
<td>3.5 (1.1)</td>
<td>3.7 (1.0)</td>
<td>4.0 (1.0)</td>
</tr>
<tr>
<td>Baseline csDMARD use, %</td>
<td>25.7</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td>CRP (mg/L), median (IQR)</td>
<td>8 (2-20)</td>
<td>7.8 (2-20)</td>
<td>18 (6.7-32.6)</td>
</tr>
<tr>
<td>Enthesitis, %</td>
<td>50.3</td>
<td>16.7</td>
<td>33.9</td>
</tr>
<tr>
<td>- Methotrexate</td>
<td>0</td>
<td>45</td>
<td>0</td>
</tr>
<tr>
<td>- Sulfasalazine</td>
<td>0</td>
<td>68</td>
<td>0</td>
</tr>
<tr>
<td>- Leflunomide</td>
<td>0</td>
<td>8</td>
<td>0</td>
</tr>
</tbody>
</table>

**Figure 1. Retention rate of TNFi monotherapy vs TNFi and csDMARD comodality, stratified by each country's one-year retention rate being above (stratum A) or below (stratum B) the average one-year retention rate.**

### Results

The majority of included patients was female (63.8%). Patient characteristics, like the presence of the HLA-B27 antigen and number of SpA-features were presented.

### Discussion

Anne Gitte Loft Grant/research support from: Novartis, Consultant of: AbbVie, MSD, Novartis, Pfizer and UCB, Speakers bureau: AbbVie, MSD, Novartis, Pfizer, Roche, Sandoz, Roche and UCB.

- Speakers bureau: AbbVie, Celgene, Lilly, Novartis, Pfizer, Roche, Sanofi, Sandoz, Roche.
- Speakers bureau: AbbVie,neapolis, Biogen, Eli Lilly, Medis, MSD, Novartis, Pfizer, Roche, Sanofi, Sandoz, UCB.
- Speakers bureau: AbbVie and consulting fees from AbbVie, Amgen, Biogen, Eli Lilly, Medis, MSD, Novartis, Pfizer, Roche, Sanofi, UCB, MSD, Maria Jose Santos
- Speakers bureau: Novartis and Pfizer, Manuel Pombo-Suarez Consultant of: Janssen, Lilly, MSD and Sanofi.
- Speakers bureau: Janssen, Lilly, MSD and Sanofi.

### Methods

The PrevAS study is a randomized, double blind, placebo-controlled trial with ETANERCEPT in patients suspected of non-radiographic axial spondyloarthritis.

**Background:** Despite the new classification criteria for non-radiographic axial spondyloarthritis (na-axSpA) patients according to the Assessment of Spondyloarthritis International Society (ASSAS), there are limited data on disease progression in na-axSpA patients.

**Objectives:** First to assess the improvement in disease activity in patients suspected of na-axSpA after 16 weeks treatment with Etanercept (ETN) or Placebo (PBO). Second, to assess the changes of active inflammation on MRI of the SI-joints (SI) between the ETN and PBO group after 16 and 24 weeks without study medication.

**Methods:** The RAAS study is a randomized, double blind, placebo-controlled trial with ETN performed in the VU University medical center (VUMc) (EudraCT number 2009-015515-40), with a screening period from 2009 until 2014. Patients suspected of na-axSpA were included if they had chronic back pain for ≥ 3 months, were ≥ 18 years, fulfilled the Calin criteria of inflammatory back pain and had to be either HLA-B27 positive with at least ≥ 1 Spondyloarthritis (SpA)-feature (as defined by the European Spondyloarthropathy Study Group ≥). Despite the new classification criteria for non-radiographic axial spondyloarthritis (na-axSpA) patients according to the Assessment of Spondyloarthritis International Society (ASSAS), there are limited data on disease progression in na-axSpA patients. Patients suspected of na-axSpA after 16 weeks treatment with Etanercept (ETN) or Placebo (PBO). Second, to assess the changes of active inflammation on MRI of the SI-joints (SI) between the ETN and PBO group after 16 and 24 weeks without study medication.

**Methods:** The PrevAS study is a randomized, double blind, placebo-controlled trial with ETN performed in the VU University medical center (VUMc) (EudraCT number 2009-015515-40), with a screening period from 2009 until 2014. Patients suspected of na-axSpA were included if they had chronic back pain for ≥ 3 months, were ≥ 18 years, fulfilled the Calin criteria of inflammatory back pain and had to be either HLA-B27 positive with at least ≥ 1 Spondyloarthritis (SpA)-feature (as defined by the European Spondyloarthropathy Study Group (ESSG), or HLA-B27 negative with at least ≥ 2 SpA-features and had a high disease activity score (Bath Ankylosing Spondylitis Disease Activity Index ≥ 4) plus sufficient response to at least two NSAIDs. Excluded were patients who fulfilled the modified New York criteria for ankylosing spondylitis, or in case of previous biological use. Included patients were randomly assigned (1:1) for 16 weeks treatment with ETN (N=40) or PBO (N=40) and followed after the treatment period for 24 weeks. The primary endpoint was the number of patients achieving the ASAS20 response at week 16. MRI was performed at baseline, 16 and 24 weeks and scored using the Spondyloarthritis Research Consortium of Canada (SPARCC) index for number of active inflammatory lesions.

**Results:** The majority of included patients was female (63.8%). Patient characteristics, like the presence of the HLA-B27 antigen and number of SpA-features were presented.
at baseline, were comparable between the ETN and PBO group. Mean compli-
ance to the study medication at sixteen weeks was 72.1%. Longitudinal regres-
sion analysis over the first 16 weeks showed a trend towards a three times higher
chance to achieve the ASAS20 response in the ETN compared to the PBO group (OR = 3.2, 95% CI [0.6,16.7] p=0.18) (Figure 1). No differences were observed
in ASAS20 response at 24 weeks. A positive SPARCC score (SPARCC ≥ 2.5)
of the SIJ was observed in the ETN and PBO group in 33.3% (13/39 patients)
vs. 30.8% (12/39 patients) at baseline, 16.7% (6/36 patients) vs. 17.5% (7/40
patients) at 16 weeks and 21.8% (7/32 patients) vs. 20.0% (7/35 patients) at 24
weeks, respectively. Increased CRP-levels (CRP_UL ≥ 10.0mg/L) nor a positive
SPARCC score at baseline, had significant influence on the ASAS20 response
at 16 weeks follow-up. The safety profile was consistent with what is known for
ETN in AS.

Conclusion: Patients suspected of n-axSpA with high disease activity showed a
trend towards a three times higher chance to achieve the ASAS20 response in the ETN
group, compared to the PBO group at 16 weeks, regardless of a raised
CRP level or positive MRI-SIJ at baseline.

Figure:

Rheumatoid arthritis - prognosis, predictors and outcome I

Acknowledgments: We thank Pfizer for financial support of this investigator
initiated study. In addition we want to thank H. Hofman and W.A. ter Wee for
practical study support.

Disclosure of Interests: Tamara Rusman: None declared, Mignon A.C. van
der Weijden: None declared, Michael T Nurmohamed Grant/research support from:
Abbvie, Bristol-Myers Squibb, Celltrion, GlaxoSmithKline, Jansen, Eli Lilly, Menarini,
Merck Sharp & Dohme, Mundipharma, Pfizer, Roche, Sanofi, USB, Consultant of:
Abbvie, Bristol-Myers Squibb, Celltrion, GlaxoSmithKline, Jansen, Eli Lilly, Menarini,
Merck Sharp & Dohme, Mundipharma, Pfizer, Roche, Sanofi, USB, Speakers bureau:
Abbvie, Bristol-Myers Squibb, Celltrion, GlaxoSmithKline, Jansen, Eli Lilly, Menarini,
Merck Sharp & Dohme, Mundipharma, Pfizer, Roche, Sanofi, Robert B.M. Landewe Consultant of: Abbvie; AstraZeneca;
Bristol-Myers Squibb; Eli Lilly & Co.; Galapagos NV; Novartis; Pfizer; UCB Pharma,
Janneke J. de Winter: None declared, B.J.H. Boden: None declared, Pierre M. Bet: None declared, Camile M.A. van der Blij: None declared, Conny
J. van der Laken: None declared, Irene van der Horst-Bruinsma Grant/research support from:
Abbvie; ViaVie, Novartis, Eli Lilly, Bristol-Myers Squibb, MSD, Pfizer, UCB Pharma,
Consultant of: Abbvie; Novartis, Eli Lilly, Bristol-Myers Squibb, MSD, Pfizer,
UCB Pharma

DOI: 10.1136/annrheumdis-2020-eular.3472

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index: Impact on quality of life using a rheumatoid arthritis cohort. Semin

Disclosure of Interests: Jeffrey Sparks Consultant of: Bristol-Myers Squibb,
Optum, Janssen, Gilead, Weixing Huang: None declared, Bing Lu: None declared,
Sicong Huang: None declared, Andrew Cagan: None declared, Vivian Gainer: None declared, Sean Finan: None declared, Guergana Savova: None declared,
Daniel Solomon Grant/research support from: Funding from Abbvie
and Amgen unrelated to this work, Elizabeth Karlson: None declared, Katherine
Liao: None declared

DOI: 10.1136/annrheumdis-2020-eular.1900

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