

The non-rheumatology led GCA pathway was associated with higher glucocorticoid burden. In this cohort, 23/55 (41.8%) patients who were found not to have GCA received more than 21 days of high dose steroids (40–60mg Prednisolone) whilst awaiting rheumatology review. 4 patients whose final diagnosis was not GCA received high dose steroids for more than 30 days (max 109 days).

**Conclusions:** 1. Availability of a rheumatology-led GCA pathway leads to improved care for patients with suspected GCA  
2. Easy access for referral of patients with headache as assessed by the non-specialist can lead to over-use of the pathway and inappropriate referrals  
3. Non-rheumatology-led GCA pathway can lead to a high glucocorticoid burden, especially in an elderly demographic with other comorbidities

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## Spondyloarthritis - treatment

### THU0345 REAL-LIFE EFFECTIVENESS OF TNF INHIBITORS IN AXIAL SPONDYLARTHROSIS: ARE CHANGING NATIONAL POLICIES ON CHOICE OF TNF INHIBITOR REFLECTED IN RESPONSE TO TREATMENT?

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**Background:** Tumour necrosis factor inhibitors (TNFi) have revolutionized treatment of axial spondylarthritis (axSpA). The five different available TNFi have not been compared directly, and whether effectiveness differs between agents is unknown. In Norway national authorities consider the different TNFi equivalent, and since 2009 the least expensive drug following an annual national tender has been the drug-of-choice in the publicly funded healthcare system. This has led to variations across different years in drug use where choice of TNFi has been predominantly based on national price policy and not clinical characteristics.

**Objectives:** Comparing response to TNFi during the first year of treatment of axSpA in biologics-naïve patients over years with highly varying uptake of different TNFi.

**Methods:** We included the 981 biologics-naïve patients with axSpA from the NOR-DMARD register who started their first TNFi from 2009 through 2015. The preferred drugs in national recommendations were: 2009 adalimumab, 2010 golimumab, 2011 etanercept, 2012 etanercept, 2013 golimumab, 2014 certolizumab, 2015 certolizumab/biosimilar infliximab (CT-P13). We compared the estimated change in Ankylosing Spondylitis Disease Activity Score (ASDAS) between treatment years at 3, 6 and 12 months after treatment start using a mixed model with subject-specific random intercept, adjusting for baseline disease activity, age, sex and treatment centre.

**Results:** Demographics, drug uptake and baseline characteristics for each year 2009–2015 are listed in table 1. The preferred drug was started in 57–91% of patients. There was a trend towards lower ASDAS and disease duration over time. There were no differences in treatment effectiveness between the years, regardless of the substantial differences in type of TNFi used (figure).

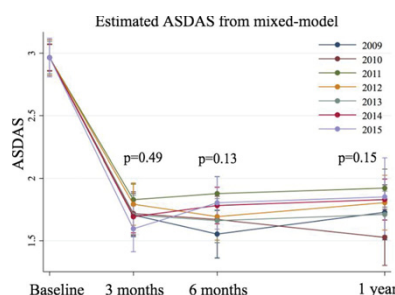
**Conclusions:** Real-life data do not show differences in response to TNFi despite large annual variation in type of TNFi prescribed, indicating similar effectiveness of the available TNFi in patients with axSpA. This supports the practice of selecting drug based on cost and feasibility of use, as is the current practice in Norway. Further adoption of this principle can provide access to TNFi treatment to more patients, as it reduces costs and healthcare resources are limited.

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**Abstract THU0345 – Table 1. Demographics and baseline characteristics**

	2009	2010	2011	2012	2013	2014	2015	p-value
N	110	104	200	124	148	192	103	
Age (years), mean (SD)	42.3 (11.2)	40.3 (11.5)	41.7 (13.0)	40.0 (12.0)	40.9 (12.7)	41.6 (11.8)	41.6 (12.3)	0.76
Proportion male	66.1%	61.2%	50.8%	55.6%	52.7%	54.7%	57.3%	0.19
Years since diagnosis, median (IQR)	4.51 (0.77, 14.69)	3.79 (0.61, 12.74)	2.63 (0.47, 12.88)	1.70 (0.56, 11.08)	0.76 (0.22, 6.78)	0.60 (0.19, 3.44)	1.41 (0.18, 10.76)	<0.001
ASDAS, mean (SD)	3.26 (0.84)	3.20 (0.92)	3.10 (0.94)	2.96 (1.01)	3.02 (0.87)	2.87 (0.89)	2.71 (1.01)	<0.001
Adalimumab	90.9%	29.8%	22.0%	14.5%	24.3%	12.0%	0.0%	<0.001
Certolizumab	0.0%	1.9%	0.0%	0.8%	12.8%	77.1%	49.5%	
Etanercept	7.3%	8.7%	63.5%	69.4%	4.7%	2.6%	1.9%	
Golimumab	0.0%	58.7%	11.0%	11.3%	57.4%	2.6%	4.9%	
Infliximab	1.8%	1.0%	3.5%	4.0%	0.7%	0.5%	0.0%	
Biosimilar infliximab	0.0%	0.0%	0.0%	0.0%	0.0%	5.2%	43.7%	

p-values for between-year differences.



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### THU0346 CONCOMITANT FIBROMYALGIA IN AXIAL SPONDYLOARTRITIS HAS A NEGATIVE IMPACT ON TNF ALPHA BLOCKERS TREATMENT EFFECT IN REAL LIFE

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**Background:** Coexisting fibromyalgia (FM) in axial spondyloarthritis (axSpA) can represent therapeutic challenges, particularly when evaluating the treatment effect of biologics (i.e. TNF alpha blockers (TNFb)). Indeed, since FM patients often report high levels of pain and disability there is the risk of classifying such patients as refractory to TNFb (ie, as not reaching a significant improvement in disease activity).

**Objectives:** To evaluate the impact of concomitant FM on the TNFb treatment effect in axSpA.

**Methods:** Design: Prospective observational national study with 2 visits 3 months apart (baseline and 12 weeks after TNFb initiation) (Predict-SpA study ClinicalTrials.gov: NCT03039088). **Patients:** axSpA patients (diagnosis according to treating rheumatologist) initiating a TNFb. **Data collection:** the FIRST questionnaire (Fibromyalgia Rapid Screen Test) which screens for FM, patients and disease characteristics and effectiveness measures (e.g. ASAS response components). **Statistical analysis:** FM positive screening was defined by a FIRST score  $\geq 5/6$ ; the primary efficacy outcome was the ASAS 40. Non-responder imputation and baseline observation carried forward imputation (for binary and continuous outcome variables, respectively) was performed. Impact of FM on the TNFb treatment effect was evaluated by multivariable logistic regression, with ASAS 40 as the dependent variable and FM as the independent variable; were also included in the model other factors previously reported in the literature as associated with treatment efficacy (i.e. X-ray and MRI sacroiliitis, abnormal CRP ( $>6\text{mg/L}$ ), HLA B-27, smoking status, previous TNFb exposure, age  $<40$  and male gender).

**Results:** Among the 527 patients enrolled in the study, 508 patients were analysed. Mean age was 41.4 ( $\pm 11.6$ ), 237 (46.7%) were women, with a 6.1  $\pm$  8.5 mean disease duration. Among them, 192 (37.8%) were screened as FM by the FIRST questionnaire. Overall efficacy of the TNFb was good (ASAS40, 201/508 (39.6%)) though 50 patients (9.8%) patients discontinued the TNFb before the follow-up visit and were considered as non-responders.

Patients with FM presented less frequently an ASAS 40 response (87/192 (45.3%) vs 171/316 (54.1%)), for the FM vs non-FM groups according to the FIRST definition. Presence of FM was independently associated with poorer ASAS40 response (adjusted odds ratio, OR = 0.5 [95% CI 0.3 – 0.8]) while X-ray sacroiliitis (1.8 [1.2 – 2.8]), abnormal CRP (1.6 [1.0 – 2.4]) and absence of previous exposure to TNFb (1.7 [1.1 – 2.6]) were found to be associated with an ASAS40 response.

**Conclusions:** This study 1) confirms the “conventional” predisposing factors of TNFb treatment response such as X-ray sacroiliitis, abnormal CRP and absence of previous exposure to TNFb; and 2) suggests that concomitant FM influences treatment response. FM deserves to be screened in axSpA, in particular in case of a decision to initiate a TNFb therapy.

**References:**

[1] Perrot S, Bouhassira D, Fermanian J; Cercle d'Etude de la Douleur en Rhumatologie. Development and validation of the Fibromyalgia Rapid Screening Tool (FIRST). Pain. 2010;150:250–6.