



## PRAGMATIC RANDOMIZED MULTICENTER OPEN-LABEL STUDY OF STOPPING TNF-INHIBITORS IN RHEUMATOID ARTHRITIS PATIENTS WITH REMISSION OR STABLE LOW DISEASE ACTIVITY IN THE NETHERLANDS

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### BACKGROUND

**The POET study is one of the first studies of discontinuing TNFi in RA patients with remission or stable low disease activity and probably the largest.**

Given the potential risk of serious side-effects and complications and the high costs of TNFi, it is important to examine whether patients in remission or stable low disease activity can effectively stop TNFi. Additionally, it is not yet clear whether TNFi can be restarted effectively and safely.

#### Baseline characteristics

	Stop TNFi (n=531)	Continuing TNFi (n=286)
Female	68.2%	66.0%
Mean age (SD), y	60.0 (11.8)	59.7 (10.6)
Mean disease duration (SD), y	12.0 (8.8)	11.1 (8.4)
Mean DAS28 (SD)	1.90 (0.76)	1.99 (0.75)
RF positive	67.5%	67.4%
Anti-CCP positive	68.3%	67.8%
Erosions	62.8%	57.6%
Adalimumab	51.1%	45.1%
Etanercept	40.2%	46.5%
Infliximab	4.7%	4.9%
Golimumab	2.8%	2.8%
Certolizumab	1.1%	0.7%
DMARD		
Methotrexate	86.4%	88.1%
Other DMARD	7.9%	8.0%
No DMARD	5.6%	3.8%

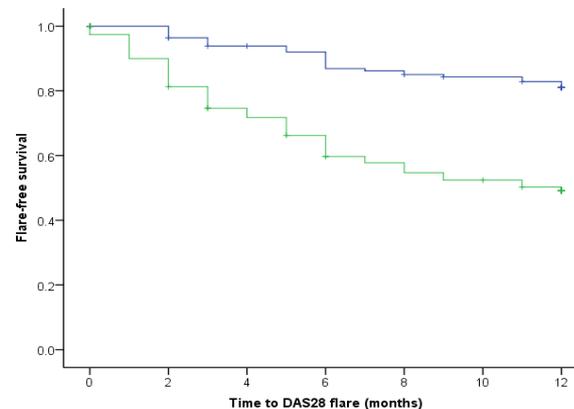
### METHODS

Pragmatic multicenter open-label randomized study. Patients were randomized to either stop or continue their current TNFi in a 2:1 ratio. Decision of flare was at the discretion of the attending physician. DAS28 flare was defined as DAS28  $\geq 3.2$  with an increase  $\geq 0.6$  compared to the previous DAS28. In case of flare in the stop group, TNFi could be restarted.

#### Inclusion criteria:

- Diagnosis of rheumatoid arthritis (RA) according to the ACR 1987 criteria.
- TNFi use for at least 1 year with stable dose DMARDs for at least 6 months.
- Low disease activity in the 6 months prior to inclusion, with at least 2 DAS28 scores  $< 3.2$  in this period.

#### Flare free survival over time.



**Kaplan-Meier curves for DAS28 flare-free survival.** The green line represents the stop group, the blue line shows the continuation group.

### RESULTS

- In total 817 patients from 47 centers were included: 531 patients (65%) in the stop group and 286 patients (35%) in the continuation group.
- At 6 months, significantly more patients in the stop group (212/531 [31,5%]) had experienced a flare than in the continuation group (36/286 [9,8%],  $p < 0.001$ )
- At 12 months these were 267/531 [50,3%] vs 52/286 [18,2%], respectively ( $p < 0.001$ ).
- The hazard ratio for flare after stopping TNFi was 3.41 (95% CI: 2.53–4.59).
- Mean DAS28 scores were significantly increased throughout the follow-up period compared with the continuation group ( $p < 0.001$ ).
- Most patients (84,6%) regained low disease activity within 6 months after a flare.
- Median time to regained low disease activity in the stop group after flare was 12 weeks (95% CI 10,8–13,2).
- There were no allergic reactions among the patients in the stop group that restarted TNFi.
- SAEs in stop vs. continuation groups: Deaths 0 (0%) vs. 1 (0,3%) and hospitalization due to infections 11 (2%) vs. 4 (1,4%), respectively.

### CONCLUSION

Stopping TNFi treatment in RA patients in remission or stable low disease activity results in substantially more flares than continuing.



POET study

Dutch Society for Rheumatology

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