

# KSN 2016 Abstract Submission

## *CKD & associated complications*

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The comparison of febuxostat and allopurinol in chronic gout patients with chronic kidney disease, a randomized prospective study.

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**Background:** The aim of this 12-week, open-label, non-inferiority trial was to compare the safety and efficacy of febuxostat with allopurinol in treating chronic gout patients with chronic kidney disease (CKD).

**Methods:** Patients were randomized to febuxostat (n= 53; 40mg daily for the first 4 weeks, 80mg thereafter) or allopurinol (n=53; dose adjusted based on ones kidney function), and both groups were stratified by baseline serum uric acid (SUA) 10.0 mg/dL. SUA was checked for 4 times (week2, 4, 8, 12) The primary end point was the proportion of SUA below 6.0 mg/dL at the end of the study. The non-inferiority margin for the difference in rates (*of SUA below 6.0 mg/dL*) was defined as -15 %. Efficacy analyses were done both by intention-to-treat (ITT) and per protocol (PP).

**Results:** Uric acid control with febuxostat (n= 49, 94.2 %) was non-inferior to that achieved with allopurinol (n= 13, 26 %), difference 0.68 [97.5 % CI 0.54 to ∞]. The proportion of SUA below 6.0 mg/dL at week 2 was 57.69 % (febuxostat) and 12% (allopurinol), respectively. And the rate increased in both group to 94.23 % (febuxostat), 26 % (allopurinol) at week 12 (p<0.0001). The rate of GFR change or incidence of AKI had no difference in both group. Skin eruption was observed in 1 case with allopurinol, but was tolerable.

**Conclusion:** Febuxostat was as effective as allopurinol in reducing SUA in chronic gout patients with CKD, with a similar safety profile.

**Table:** Table 1. Baseline characteristics of the participants

	Febuxostat (N=53)	Allopurinol (N=50)	p-value
Age, mean (SD), year	54.53 (5.31)	57.66 (13.54)	0.3764
Sex, male (%)	48 (90.57)	45 (90.00)	1.0000
Height, mean (SD), cm	168.9 (7.66)	166.63 (7.77)	0.0880
Weight, mean (SD), kg	74.65 (15.71)	69.79 (11.53)	0.0827
Serum uric acid, mean (SD), mg/dL	9.07 (1.53)	8.77 (1.58)	0.3301
CKD stage, N(%)			0.8246
1	3 (5.66)	2 (4)	
2	9 (16.98)	7 (14)	
3	32 (60.38)	29 (58)	
4	9 (16.98)	12 (24)	

Drinking (%)	16 (30.19)	19 (38.00)	0.4029
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Table 2. The proportion of serum uric acid (SUA) below 6.0 mg/dL at 12-week

	<b>Febuxostat</b>	<b>Allopurinol</b>	<b>p-value</b>
<b>ITT</b>	52	50	
<b>SUA &lt; 6.0 mg/dL</b>	49	13	< 0.0001
Initial SUA < 10 mg/dL	31 (93.94)	10 (33.33)	< 0.0001
Initial SUA > 10 mg/dL	18 (94.74)	3 (15.00)	< 0.0001
<b>PP</b>	46	44	
<b>SUA &lt; 6.0 mg/dL</b>	45	13	< 0.0001
Initial SUA < 10 mg/dL	28 (100.00)	10 (38.46)	< 0.0001
Initial SUA > 10 mg/dL	17 (94.44)	3 (16.67)	< 0.0001

**Keywords:** chronic kidney disease, Febuxostat, gout