EULAR review

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#EULAReview23

Sociedad Española de Reumatología

Enfermedades Autoinmunes Sistémicas: LES, Sjögren y Esclerodermia

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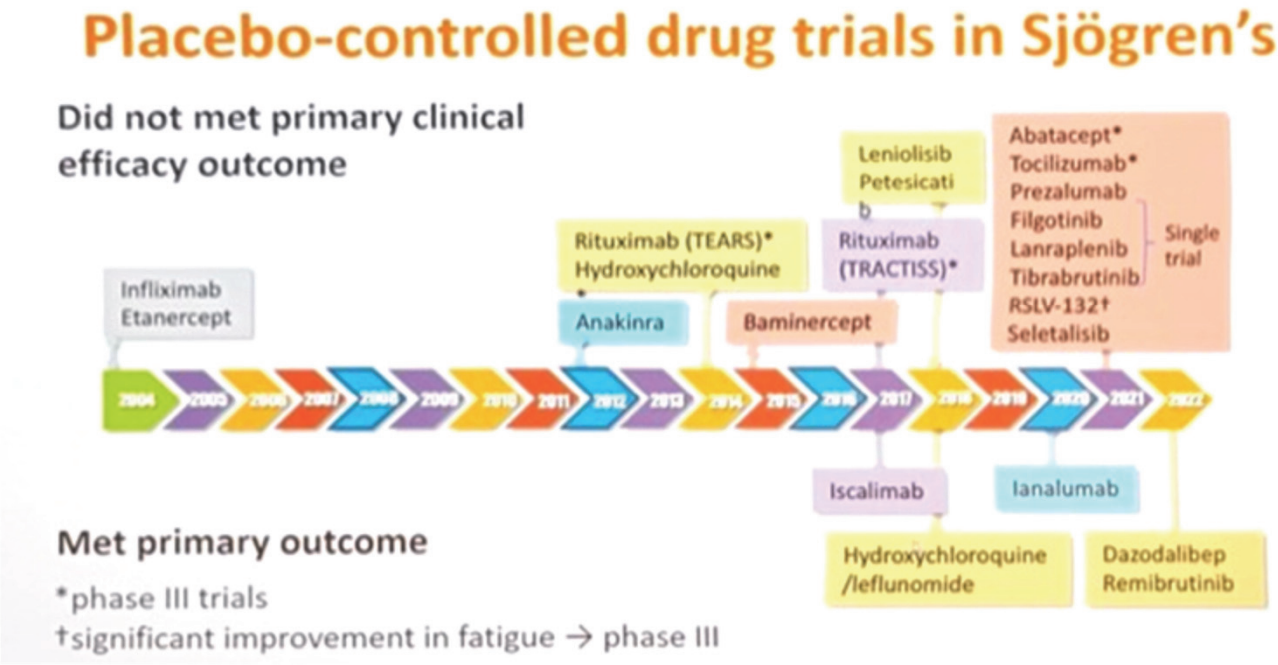
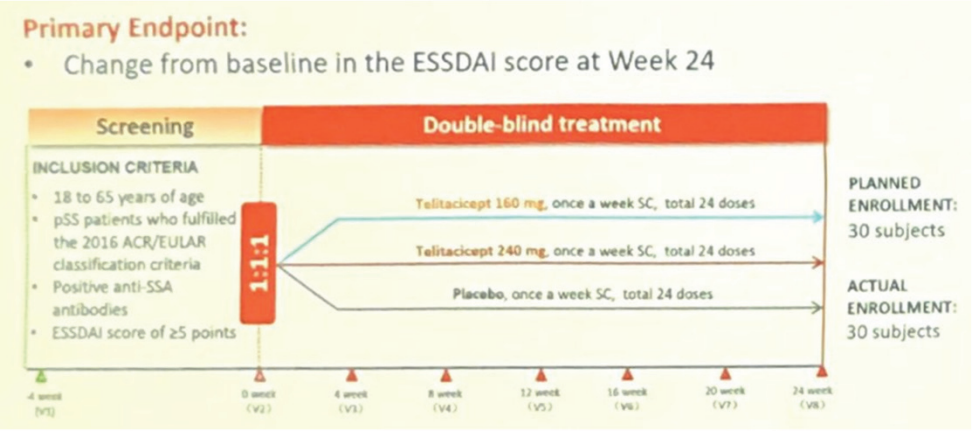
OP0142

Efficacy and Safety of telitacicept, a novel BLyS/APRIL dual inhibitor, in patients with primary Sjögren's syndrome: a phase 2, randomized, placebo-controlled 24-week study



Von Vollenhoven et al

Efficacy and Safety of telitacicept, a novel BLyS/APRIL dual inhibitor, in patients with primary Sjögren's syndrome: a phase 2, randomized, placebo-controlled 24-week study



Baseline Demographics and Disease Characteristics

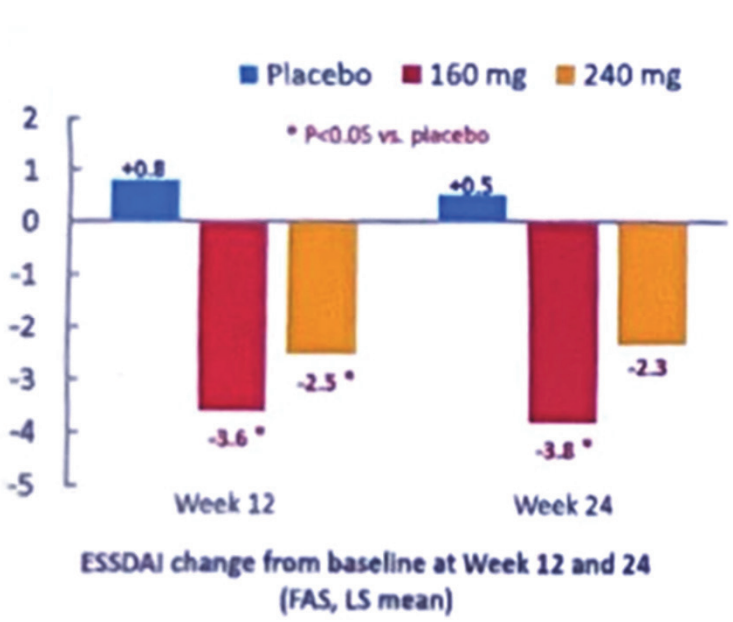
	Placebo (N=14)	Telitacicept 160 mg (N=14)	Telitacicept 240 mg (N=14)
Female, n(%)	13 (92.9%)	13 (92.9%)	14 (100.0%)
Age (years), mean (SD)	48.7 (13.5)	47.4 (12.4)	52.1 (11.8)
BMI (kg/m²), mean (SD)	23.2 (2.4)	21.9 (2.3)	22.9 (2.6)
Disease duration (month), mean (SD)	31.8 (51.1)	39.1 (68.2)	32.1 (48.8)
ESSDAI, mean (SD)	9.9 (7.0)	7.3 (2.6)	8.9 (4.7)
ESSPRI, mean (SD)	5.2 (1.8)	4.8 (2.2)	5.1 (2.3)
MFI-20, mean (SD)	50.7 (16.1)	58.9 (10.1)	59.6 (16.6)
Unstimulated salivary flow rate (g/min), mean (SD)	0.03 (0.05)	0.09 (0.10)	0.08 (0.10)
Schirmer test (left eye, mm), mean (SD)	4.1 (3.4)	4.2 (2.2)	3.5 (4.0)
Schirmer test (right eye, mm), mean (SD)	3.4 (2.5)	4.1 (2.9)	4.6 (4.5)
IgG (g/L), mean (SD)	16.3 (4.6)	19.6 (6.1)	15.9 (4.4)
IgA (g/L), mean (SD)	3.5 (1.6)	3.0 (1.2)	3.5 (1.5)
IgM (g/L), mean (SD)	1.3 (0.7)	1.2 (0.4)	1.0 (0.4)
CD19⁺ B cell (/ul) mean (SD)	193.7 (112.5)	157.8 (83.2)	189.0 (106.5)
Baseline medication use, n(%) Hydroxychloroquine sulfate	7 (50.0%)	8 (57.1%)	7 (50.0%)

ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index;

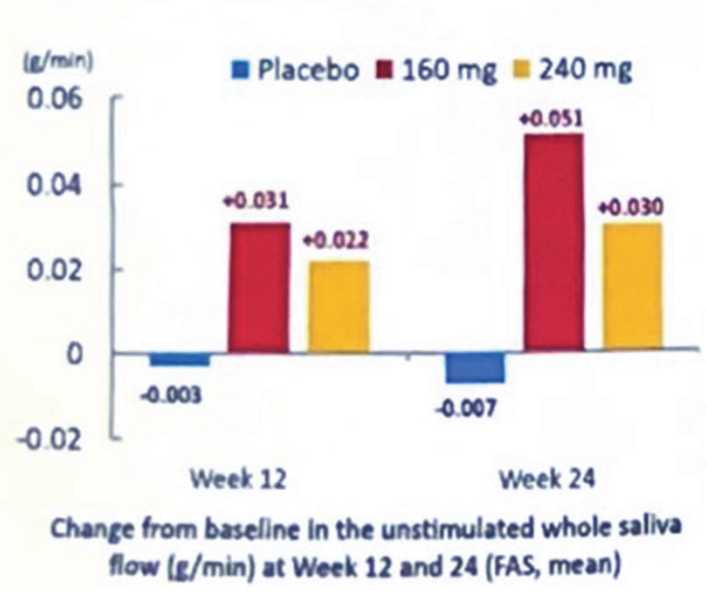
Scanned with CamScanner

Von Vollenhoven et al

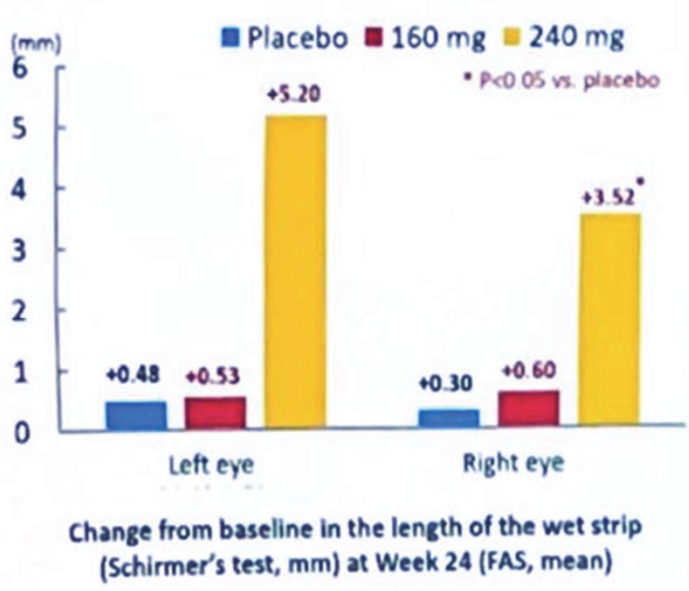
Change in ESSDAI at week 12 and 24



ESSDAI change from baseline at Week 12 and 24 (FAS, LS mean)



Change from baseline in the unstimulated whole saliva flow (g/min) at Week 12 and 24 (FAS, mean)



Change from baseline in the length of the wet strip (Schirmer's test, mm) at Week 24 (FAS, mean)

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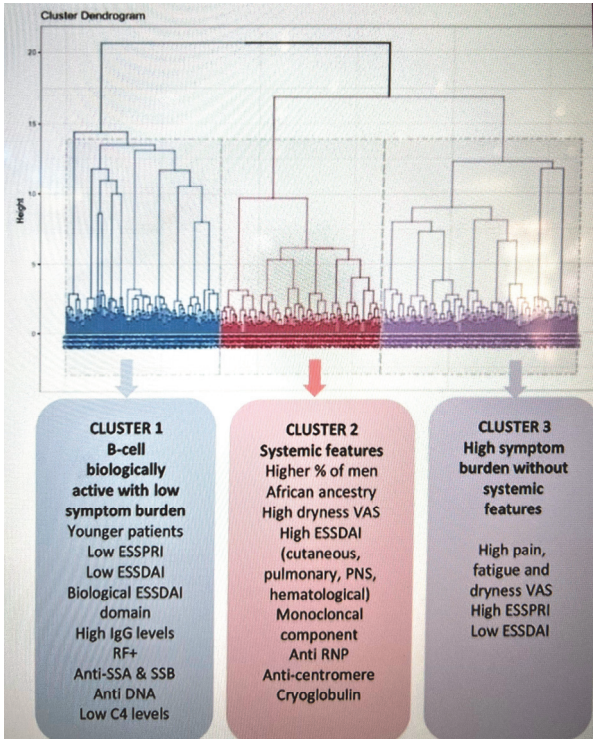
POS0165

Determination of distinct phenotypes of primary Sjögren's disease using cluster analysis based on clinical and biological manifestations: data from 458 patients from the Paris Saclay Sjögren's Syndrome Cohort

Characteristic	Overall, N = 534[1]
Age at SjS diagnosis*	54 (43, 64)
Gender = Male	32 (6.0%)
Ethnicity*	
African	33 (6.2%)
Asian	34 (6.4%)
Caucasian	467 (87%)
Patient-reported outcomes	
Pain VAS *	51 (20, 77)
Fatigue VAS*	62 (40, 80)
Overall dryness VAS	61 (40, 77)
ESSPRI score	5.7 (4.1, 7.1)
Systemic manifestations	
Constitutional*	6 (1.1%)
Lymphadenopathy*	29 (5.4%)
History of lymphoma	28 (5.2%)



Nguyen et al.

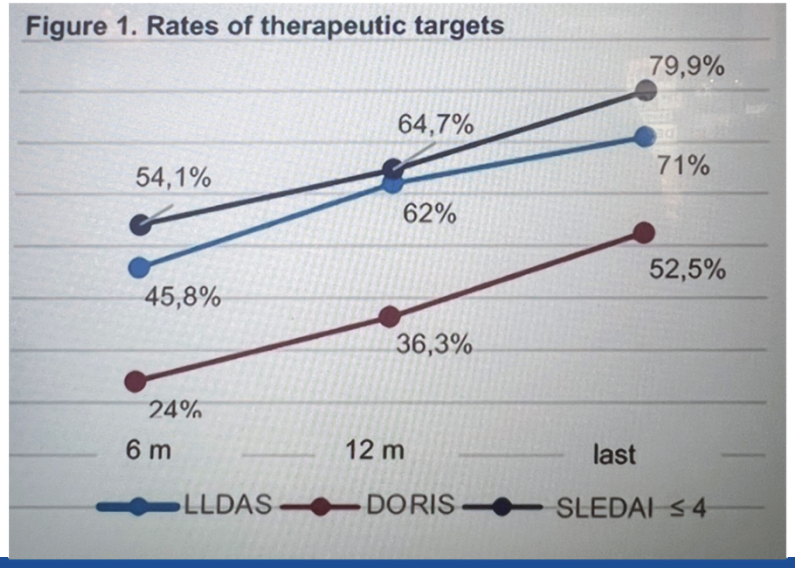
POS 1144

Effectiveness of belimumab in systemic lupus erythematosus patients of a multicentre Spanish cohort.

Altabas I et al

A longitudinal retrospective multicenter conort including SE patients treated wilh belimumab from 18 Spanish rheumatology departments

- **324** patients (91% females with a mean (‡SD) age of 42.4 vears
- Mean follow-up was 3,8 (+2.7) years and mean time with BLM was 2.7 (+2.4) years.



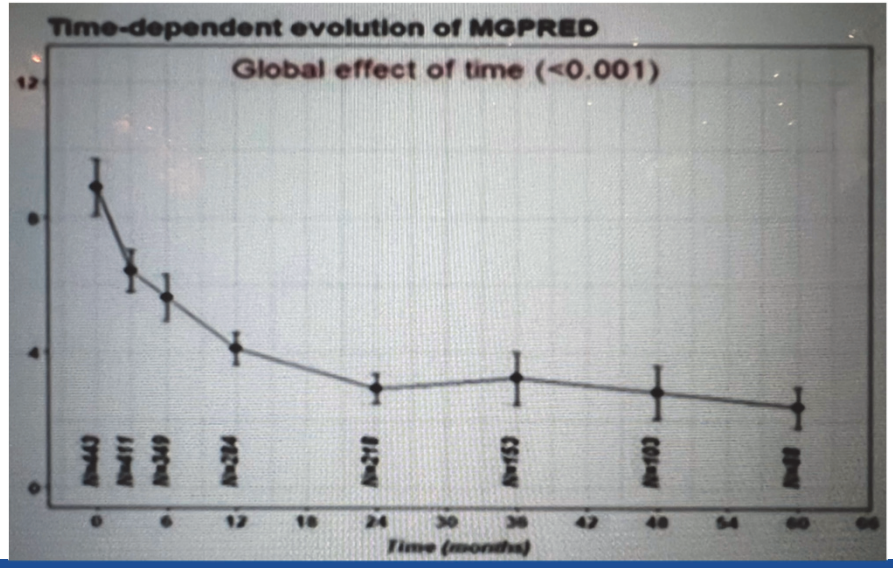
POS 1142

Spanish National Regsitry Of Belimumab In Patients With SLE.

Aldasoro V et al

- A total of **462** patients (36 hospitals) were included, 50.9% were on intravenous (IV), 34% on subcutaneous (SC) and 15.1% switched from IV to SC route.

Significant decrease in prednisone dose, SLEDAI and DNA was observed from baseline until the last visit



OP0051

Lupus Low Disease Activity State Attainment in the Phase 3 Placebo-controlled TULIP Long-term Extension Trial of Anifrolumab. Moreland E.

Objectives:

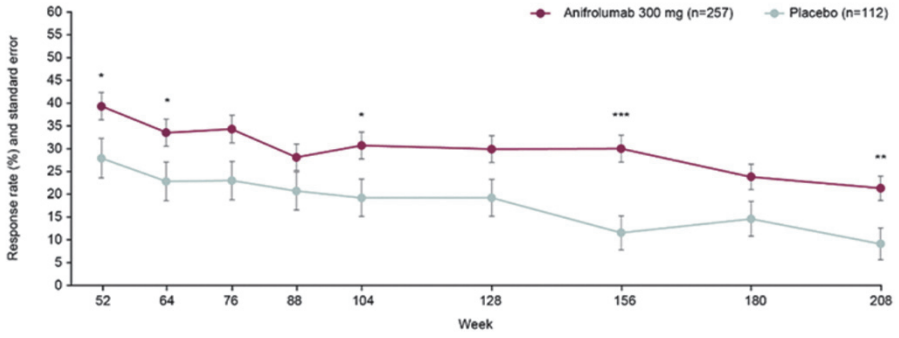
- We investigated the long-term impact of anifrolumab compared with placebo on LLDAS attainment over the 1 year TULIP-1/TULIP-2 and 3 year long-term extension (LTE) study periods

Results:

- Data from 369 patients (anifrolumab 300 mg, n=257; placebo, n=112) were evaluable for the 4-year TULIP+LTE study period.
- At the last TULIP visit (Week 52), 39.3% of the anifrolumab group and 27.9% of the placebo group were in LLDAS (odds ratio [OR] 1.6, 95% CI 1.0–2.7, P=0.049).

Compared with placebo, patients treated with anifrolumab were more likely to be in sustained LLDAS for ≥3 consecutive visits (49.4% vs 35.1%; OR 1.8, 95% CI 1.1–2.8, P=0.018), ≥5 consecutive visits (32.6% vs 20.1%; OR 1.8)

Figure. Lupus Low Disease Activity State (LLDAS) response rate and percentage of patients with no IP discontinuation by randomized treatment in patients with SLE in the TULIP long-term extension study

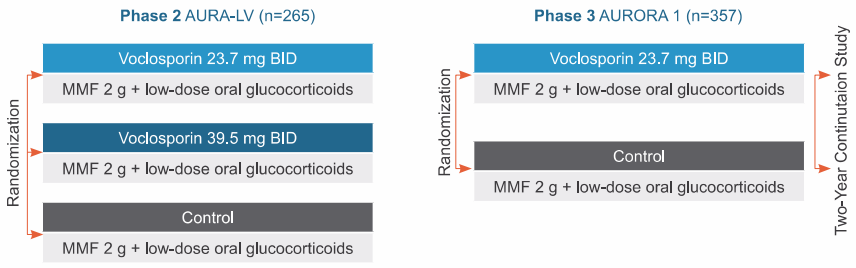


POS0116

Efficacy and Safety of Voclosporin across Patient Subgroups with Proteinuria ≥2 mg/mg : An Integrated Analysis of the AURA-LV and AURORA 1 Studies. Stone A et al.

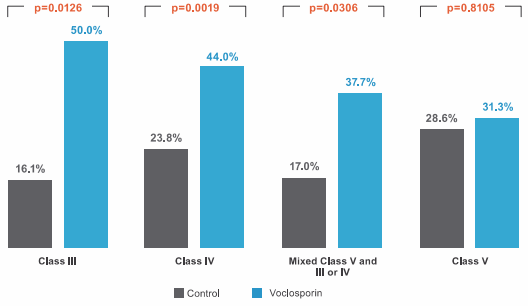
STUDY DESIGN: AURA-LV & AURORA 1

- AURA-LV and AURORA 1 were one-year, global, double-blind, randomized clinical trials with similar designs and endpoints that evaluated the efficacy and safety of voclosporin 23.7 mg twice daily (BID) compared to placebo when used in combination with MMF and low-dose oral glucocorticoids in a diverse population of patients with active LN[8-10]



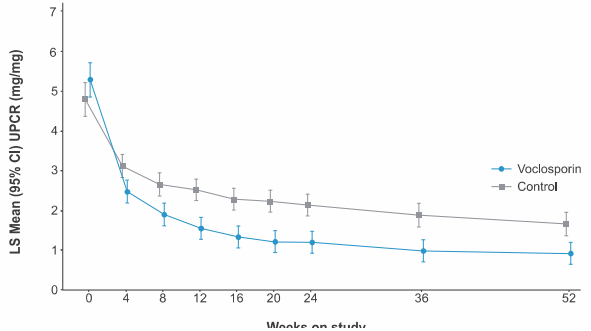
COMPLETE RENAL RESPONSE RATES BY BIOPSY CLASS

- Across biopsy classes, the highest rates of CRR were observed in voclosporin-treated patients with Class III and Class IV disease



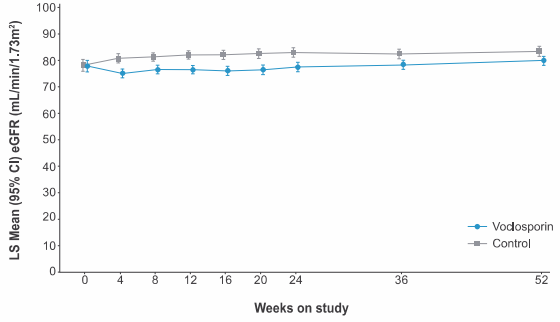
PROTEINURIA

- At one year, the change from baseline in least squares (LS) mean (standard error [SE]) UPCR was -3.8 (0.1) mg/mg in the voclosporin arm compared to -3.1 (0.2) mg/mg in the control arm (difference vs. control, -0.7; p=0.0003)



eGFR

- After an expected, small decrease in eGFR in the voclosporin arm due to the hemodynamic effect of CNIs, LS Mean corrected eGFR was stable over one year of treatment in both arms

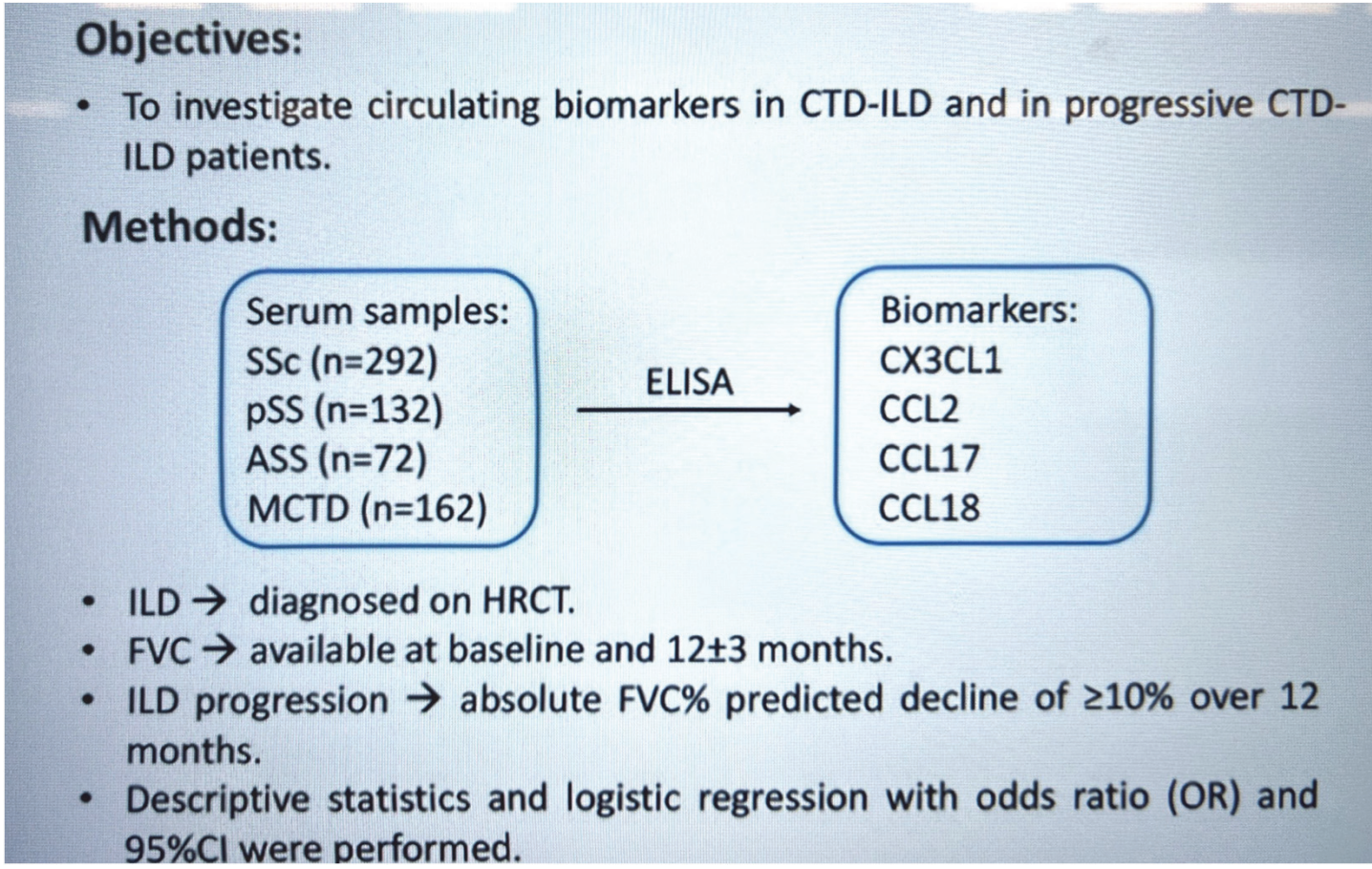


Voclosporin (n)	217	214	200	199	196	186	179	168	144
Control (n)	215	211	206	199	190	184	177	159	157

POS0122

Investigation of serum marker levels in connective tissue diseases developing ILD.

Didriksen H et al.



	SSc (n=292)	pSS (n=132)	ASS (n=72)	MCTD (n=162)
Females, no (%)	239 (61)	123 (93)	48 (67)	128 (79)
Age at disease onset, years (SD)	48 (15.4)	52 (14.1)	49 (12.8)	35 (15.7)
FVC baseline, % (SD)	95 (20.3)	99 (12.7)	85 (21.8)	92 (18.5)
ILD, no (%)	140 (47.9)	16 (12.1)	60 (83.3)	51 (31.5)
ILD progression, n (%)	74 (26)	3 (19)	3 (6)	-

	CX3CL1	CCL2	CCL17	CCL18
CTD compared to HC:				
SSc	▲	▲	▲	▲
pSS	▲	—	—	▲
ASS	▲	▲	▲	▲
MCTD	▲	▲	▲	▲
CTD-ILD compared to no-ILD:				
SSc-ILD	▲	▲	▲	▲
pSS-ILD	▲	▲	▲	▲
ASS-ILD	—	—	▲	—
MCTD-ILD	—	—	—	—

Logistic regression analysis of the patient with ILD progression showed that CCL18 (OR: 1.19, 95%CI, p=0.001) was the only marker significantly associated with ILD progression, also when adjusting for CTD with SSc as reference disease (OR: 1.06, 95%CI: 1.03-1.09, p<0.001) (Figure 2).

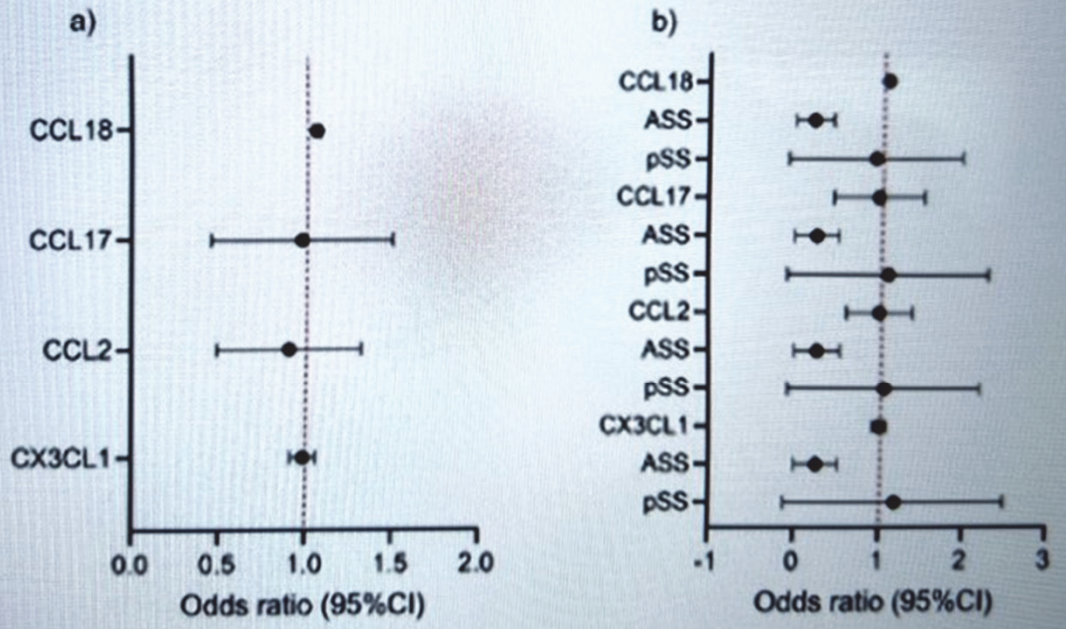


Figure 2: Association of circulating markers with ILD progression using SSc-ILD as the reference.

Didriksen H et al.

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