SIMPONI® (subcutaneous golimumab)
Use of SIMPONI in the Treatment of Uveitis

SUMMARY

- The company cannot recommend any practices, procedures, or usage that deviate from the approved labeling.
- Open-label studies, retrospective studies, and a retrospective case series have described the use of SIMPONI in patients with refractory uveitis.[1-9]

CLINICAL DATA

Open-Label Studies

Domínguez-Casas et al (2017)[1] conducted a multicenter study comparing SIMPONI vs tocilizumab in treating uveitis related to juvenile idiopathic arthritis (JIA).

Study Design/Methods

- Patients included were refractory to conventional treatment with high dose corticosteroids and at least 1 conventional immunosuppressive systemic treatment and 1 anti-tumor necrosis factor α (TNF-α) therapy.
- Treatment with tocilizumab or SIMPONI 50 mg subcutaneous (SC) monthly was initiated.
- Outcomes assessed were visual acuity (VA), vitreous inflammation, degree of intraocular inflammation and macular thickening (by optical coherence tomography [OCT]).

Results

Patient Characteristics

- Sixty-one affected eyes from 33 patients (mean age 18.5 years) were evaluated.
- Twenty-five patients received tocilizumab and 8 patients received SIMPONI.

Efficacy

- Table: Ocular Parameters shows the ocular parameters for SIMPONI in this study.

Ocular Parameters[1]

	SIMPONI (n=8)
Baseline	
VA	0.5±0.36
Cells in the anterior chamber	2.79±4.82
Vitritis	0.33±0.5
OCT	313.60±77.05
First month	
VA	0.56±0.32
Cells in the anterior chamber	2.33±4.57
Vitritis	0±0
OCT	292.50±111.42
Sixth month	
VA	0.62±0.33
Cells in the anterior chamber	0±3.28
Vitritis	0.25±0.62
OCT	261.37±75.15
First year	
VA	0.54±0.31
Cells in the anterior chamber	0±0
Vitritis	0±0
OCT	255±120.8

Abbreviations: OCT, optical coherence tomography; VA, visual acuity.

Safety

- After a mean follow-up of 24.25±17 months with SIMPONI treatment, cutaneous reaction was observed in 2 patients.

Calvo-Río et al (2016)[2] conducted an open-label, multicenter study evaluating the efficacy of SIMPONI in refractory uveitis related to spondyloarthritis (SpA).

Study Design/Methods

- Patients received SIMPONI 50 mg monthly.
- The main outcomes measured were intraocular inflammation, macular thickness (by OCT), best corrected visual acuity (BCVA), and sparing corticosteroid effect. These were measured in most patients at baseline, and at 1 week, 2 weeks; 1 month, 3 months, 6 months; and 1 year and 2 years.

Results

Patient Characteristics

- Eighteen affected eyes from 15 patients with SpA-related uveitis were treated with SIMPONI.
- Ankylosing spondylitis (AS; n=8) was the most frequent underlying SpA subtype followed by psoriatic arthritis (PsA; n=6) and nonradiographic axial SpA (n=1).
- Of the 15 patients, 8 patients had recurrent anterior uveitis and 7 patients had chronic anterior uveitis.
- Patients were refractory to at least 1 immunosuppressive drug.
- Ten of 15 patients had previously been treated with TNF-α blockers; adalimumab (n=7), etanercept (n=7), infliximab (n=6), and certolizumab (n=1).
- SIMPONI was given as monotherapy (n=7) or in combination with conventional immunosuppressive drugs (n=8), mainly methotrexate (MTX).

Efficacy

- Treatment with SIMPONI showed a rapid and maintained improvement in macular thickness and BCVA.
- After 2 years of treatment with SIMPONI, mean BCVA increased from 0.62±0.3 to 0.84±0.3 (P=0.03).
- For intraocular inflammation parameters (anterior chamber cells [ACC], vitritis, and OCT >250 µm), most patients had rapid and progressive improvement. The median number of cells in the anterior chamber at 2 years (0 [interquartile range, IQR; 0-0]) was significantly reduced compared to baseline findings (1 [IQR, 0-3]; P=0.04).
- Improvement was seen in OCT values which improved from 295±42.2 µm at baseline to 259.2±10.3 µm after 2 years of receiving SIMPONI (P=0.36).
- A corticosteroid sparing effect was observed as the mean daily dose of prednisone was reduced from 34.4±19.4 mg at baseline to 9.2±7.3 mg at 2 years (P=0.04).
- SIMPONI dose was increased to 100 mg SC every 4 weeks in 1 patient after 4 months of therapy due to a new outbreak of uveitis.
- Thirteen patients achieved complete clinical remission after a median follow-up of 23±7 months.

Safety

- One patient discontinued SIMPONI after 36 months of treatment after being diagnosed with renal adenocarcinoma.
- Another case reported a mild facial herpes zoster local injection-site reaction which was treated favorably with oral antiviral therapy.

Santos-Gómez et al (2014),[3] in a multicenter study, evaluated the efficacy and safety of SIMPONI in patients with noninfectious uveitis refractory to standard synthetic immunosuppressive medications and at least 1 anti-TNF-α agent.

Study Design/Methods

- The dose of SIMPONI was 50 mg monthly.
- The main outcomes measured were degree of anterior and posterior chamber inflammation, VA, and macular thickness.

Results

Patient Characteristics

- In the study, there were 29 patients (21 male, 8 female) who represented 44 affected eyes, and uveitis was bilateral in 15 cases and unilateral in 14 cases.
- The pattern of ocular involvement was anterior uveitis (n=19), panuveitis (n=6), and intermediate, anterior + intermediate, anterior + posterior and intermediate + posterior were all 1 case each.
- The patients' uveitis was chronic (n=16), recurrent (n=12), or acute (n=1).
- SIMPONI was initiated due to inefficacy (n=27) and/or toxicity (n=2) to other biologics and was used as monotherapy (n=11) or in combination with other therapy (MTX [n=10], azathioprine [AZA, n=4], leflunomide [n=2], mycophenolate [n=2]).

Efficacy

- The following outcomes reported were after 1 year of SIMPONI therapy.
- The mean BCVA improved from 0.68±0.3 at baseline to 0.75±0.3 (P<0.05).
- Anterior chamber and vitreous inflammation improved from 62.7% and 40.4% of eyes, to 12.5% and 0%, respectively (P<0.05).
- Cystoid macular edema (OCT>300 μm) improved from 50% to 0% (P<0.05).
- The mean OCT improved from 318.9±76 μm to 244.2±43.2 μm (P<0.05).
- The mean dose of prednisone improved from 24±20.1 mg/day to 7.7±7.6 mg/day (P<0.05).

Safety

- Side effects reported included injection site erythema (n=3) and herpes zoster (n=1) after a mean follow-up of 13.1±8.5 months (range, 2-30 months).

Retrospective Studies

Lanz et al (2021)[9] conducted a retrospective analysis at a single-center to evaluate the efficacy of SIMPONI in 10 patients with JIA-associated uveitis refractory to at least 1 conventional disease-modifying antirheumatic drug (DMARD) and adalimumab.

Study Design/Methods

- Patients weighing ≥40 kg or ≤40 kg with a body surface area of 30 mg/m^2 were treated with SIMPONI 50 mg SC every 4 weeks.
- Intraocular inflammation (determined by ACC count), BCVA, corticosteroid-sparing potential, and ocular complications were evaluated at the start of SIMPONI treatment, at 1 month, at 3 months, and then every 3 months.
    - Response to SIMPONI treatment was classified as complete (inactive uveitis), partial (improved uveitis), or nonresponse (NR) at each time point.

Results

Patient Characteristics

- A total of 10 female patients (mean age, 14.3±6.7 years) with JIA-associated uveitis refractory to at least 1 conventional DMARD and adalimumab were included.
  - Patients received SIMPONI following primary NR to adalimumab (n=2) or loss of response to adalimumab (n=8).
  - Anterior uveitis and panuveitis was reported in 7 and 3 patients, respectively.
- Ocular complications were documented in 8 patients (macular edema, n=2; cataract, n=4; glaucoma, n=2; synechiae, n=7; band keratopathy, n=2).
- Concomitant systemic corticosteroid use and topical corticosteroid use was documented in 5 and 9 patients, respectively.

Efficacy

- Median follow-up with SIMPONI was 25.2 months.
- Response to SIMPONI treatment is summarized in Table: Uveitis Response to SIMPONI Treatment.
- A complete response to SIMPONI was seen in 5 patients at 24 and 30 months. Two patients were treated for >60 months. One patient experienced a flare at 60 months but had then responded again to SIMPONI at 66 months.

Uveitis Response to SIMPONI Treatment[9]

Patient Number	Uveitis Duration Before SIMPONI (Years)	Previous Therapy	Response to ADA	Concomitant cDMARD	Response to SIMPONI	Concomitant cDMARD	Current Biologic Therapy, Response
1	6.2	MTX, ADA	CR, LOR	-	CR	-	SIMPONI
2	4.1	MTX, AZA, ADA	PR, LOR	AZA	PR, LOR	AZA	TFC, PR
3	12.7	MTX, AZA, ETA, SSZ, IFX, MMF, TCR, IFNα, ADA	PR, LOR	-	PR	-	SIMPONI
4	1.0	MTX, ADA	CR, LOR	MTX	CR	MTX	SIMPONI
5	10.9	MTX, ADA	CR, LOR	-	CR	-	SIMPONI
6	17.4	MTX, MMF, ADA	CR, LOR	-	CR	-	SIMPONI
7	12.3	MTX, ADA	CR, LOR	-	PR, LOR	MTX	ADA, CR
8	4.8	MTX, IFX, ADA	PNR	MTX	PNR	MTX	TCZ, CR
9	17.3	MTX, AZA, IFX, MMF, ADA	PR, LOR	AZA	PR, LOR	MMF	ABA, PR
10	2.9	MTX, AZA, IFX, ADA	PNR	MTX	PNR	MTX	TCZ, CR

Abbreviations: ABA, abatacept; ADA, adalimumab; AZA, azathioprine; cDMARD, conventional disease-modifying antirheumatic drug; CR, complete response; ETA, etanercept; IFNα, interferon α; IFX, infliximab; LOR, loss of response; MMF, mycophenolate mofetil; MTX, methotrexate; PNR, primary nonresponse; PR, partial response; SSZ, sulfasalazine; TCR, tacrolimus; TCZ, tocilizumab; TFC, tofacitinib.

- No change was observed for BCVA from baseline to final visit.
- The mean dose of systemic corticosteroids was reduced from 0.19 mg/kg at baseline to 0.09 mg/kg, 0.08 mg/kg, and 0.07 mg/kg at 1, 3, and 6 months, respectively.

- Systemic corticosteroid use was documented in 1 patient each at 9 months, 18 months, and 36 months.
- Macular edema resolved in 2 patients who initially presented with this complication. New ocular complications were observed in 3 patients (macular edema, n=2; synechiae, n=2).

Safety

- SIMPONI was well tolerated in 9 patients.
- One patient developed viral infections, including herpes genitalis and reactivation of cytomegalovirus. SIMPONI was temporarily discontinued and then restarted after 2 months.

Tosi et al (2019)[4] retrospectively evaluated medical charts of patients who received SIMPONI or certolizumab pegol because of systemic inflammatory disorders associated with uveitis or owing to idiopathic uveitis.

Study Design/Methods

- The study evaluated medical charts related to patients treated with SIMPONI 50 mg SC every 4 weeks and patients treated with certolizumab pegol 400 mg for induction and 200 mg every 2 weeks thereafter because of idiopathic uveitis or uveitis related to different systemic inflammatory disorders.
- Follow-up was conducted every 3 months or when necessary (disease relapse or safety concerns).
- The primary objective of the study was to evaluate the efficacy of SIMPONI and certolizumab pegol.
- Secondary objectives were evaluate patients' persistence on therapy, examine the consequences of the drugs on VA, estimate the corticosteroid-sparing effect, and evaluate the safety profile and ocular complications during treatment.
- BCVA was assessed at every visit using the Snellen chart in decimal fractions.

Results

Patient Characteristics

- A total of 21 patients (30 eyes) were included in the analysis; 10 patients were treated with SIMPONI and 11 patients were treated with certolizumab pegol.
- The mean treatment duration was 30±29.47 months for patients treated with SIMPONI and 16.45±7.93 months for patients treated with certolizumab pegol.
- Of the 21 patients in the analysis, 7 patients (33.3%) started biologic treatment due to active or recently active (within 60 days) ocular involvement, and 14 (66.7%) patients started biologic treatment due to active or recently active (within 60 days) ocular and systemic inflammatory involvement.
- There was no evidence of active retinal vasculitis (RV) at baseline in any enrolled patient.
- Coadjuvant immunosuppressive therapy was used in 10 patients, including MTX (n=6), AZA (n=3), and cyclosporine A (n=1).
- Demographic and clinical features of patients treated with SIMPONI are summarized in Table: Demographic and Clinical Features of Patients Affected by Uveitis Treated with SIMPONI.

Demographic and Clinical Features of Patients Affected by Uveitis Treated with SIMPONI[4]

Patient Number	Gender	HLA-B51	HLA-B27	Age at Uveitis Onset	Uveitis Duration (Years)	Anatomic Pattern	Laterality	Systemic Diagnosis	Previous Therapies
1	F	+	-	30	30	PAN	BL	BS	ETN, IFX, ADA, RTX

Patient Number	Gender	HLA-B51	HLA-B27	Age at Uveitis Onset	Uveitis Duration (Years)	Anatomic Pattern	Laterality	Systemic Diagnosis	Previous Therapies
2	F	-	-	40	6	AU	ML	BS	ADA
3	F	-	-	38	1	AU	BL	BS	MTX, ADA
4	F	-	-	3	30	AU	BL	JIA	MTX, IFX, ADA
5	F	-	-	51	4	AU	ML	SpA	MTX, ETN, IFX, ADA
6	F	-	-	57	5	AU	ML	BS	MTX, IFX, ADA
7	F	+	-	50	2	IU	ML	BS	MTX, ADA
8	M	+	-	29	18	AU	ML	BS	IFX, ADA
9	M	+	-	18	20	PAN	ML	BS	AZA, ADA
10	F	-	+	26	8	AU	BL	SpA	MTX, IFX, ADA

Abbreviations: ADA, adalimumab; AU, anterior uveitis; AZA, azathioprine; BL, bilateral; BS, Behcet's syndrome; ETN, etanercept; F, female; HLA, human leukocyte antigen; IFX, infliximab; IU, intermediate uveitis; JIA, juvenile idiopathic arthritis; M, male; ML, monolateral; MTX, methotrexate; PAN, panuveitis; RTX, rituximab; SpA, spondyloarthritis.

Efficacy

- The number of ocular flares decreased from the 12 months prior to the start of SIMPONI or certolizumab pegol and the 12 months thereafter (128.6 events for 100 patients-year to 42.9 events for 100 patients-year, *P*=0.01).
- At the last follow-up visit, uveitis was inactive in 18 of 21 patients.
- During the 36 months follow-up, the SIMPONI and certolizumab pegol retention rate was 54.5% and 50.0%, respectively.
- BCVA improved in 3 eyes, worsened in 6 eyes, and did not change in 21 eyes.
- The overall BCVA was 8.71±2.22 at baseline and 8.14±2.04 at last follow-up.
- No statistically significant differences were observed in the daily prednisone (or equivalent) intake between the different time points in the study.

Safety

- A skin ulcerative lesion on the left hand occurred in a patient treated with SIMPONI which resulted in treatment discontinuation.
- Glaucoma, cataract, and macular edema were each reported in an eye treated with SIMPONI.
- No serious adverse events were reported during the study.

Yazgan et al (2017)[5] retrospectively analyzed the efficacy of SIMPONI on severe and recurrent anterior uveitis in patients with human leukocyte antigen (HLA)-B27-positive AS.

Study Design/Methods

- HLA-B27-positive AS patients with recurrent anterior uveitis accompanying severe spondyloarthropathies resistant to known treatment protocols were included.
- Data collected included the number of recurrences of anterior uveitis/year within the last year prior to starting and after treatment with SIMPONI.
- Ocular examinations included BCVA, intraocular pressure, grading of activation of uveitis according to the SUN criteria, and anterior and posterior segment findings.
- SIMPONI therapy was considered successful if the following criteria was met: remission of uveitis (disappearance of the ACC and anterior chamber flare [ACF]), reduction in the need for systemic and topical steroid treatment, no new ocular complications, reduction in number of uveitis attacks, and no new additional visual loss related to uveitis.

Results

Patient Characteristics

- Fifteen eyes from 12 HLA-B27-positive AS patients (5 male, 7 female) with anterior uveitis who received SIMPONI 50 mg SC injection once a month were included. Three cases had bilateral anterior uveitis.
- Prior to SIMPONI therapy, all patients had been applied 1 or several of the following treatments: salicyl-azo-sulfapyridine, colchicine, indomethacin, MTX, AZA, etanercept, and adalimumab.
- Median BCVA was 0.30 log to logarithm of the minimum angle of resolution (logMAR) and median ACC and ACF were grade 3 before starting SIMPONI treatment.

Efficacy

- Twelve out of 15 eyes experienced remission of uveitis.
- Ocular findings are summarized in Table: Ocular Findings of Patients Before and After Treatment of SIMPONI.
- A significant increase was seen in VA (*P*=0.002).

Ocular Findings of Patients Before and After Treatment of SIMPONI[5]

Patient	Oral Systemic Steroid Therapy (at Beginning of SIMPONI/at Last Visit) (Prednisolone mg/day)	Topical Steroid Drops Therapy (at Beginning of SIMPONI/at Last Visit) (1% Prednisolone Acetate, Daily)	BCVA (at Beginning of SIMPONI)	BCVA (at Last Visit)	Grade of Anterior Uveitis Activity at Beginning of SIMPONI (ACC/ACF)	Grade of Anterior Uveitis Activity at Last Visit (ACC/ACF)
#1	48/none	6 x 1/none	20/40	20/20	+2/+2	0/0
#2	None/none	12 x 1/none	20/40	20/25	+3/+2	0/0
#3	None/none	RE; 2 x 1/ 2 x 1 LE; 2 x 1/ 2 x 11	20/25 20/25	20/25 20/25	+1/+1 +1/+1	+2/+1 +1/+1
#4[a]	None/none	24 x 11/none	20/200	20/32	+4/+3	0/0
#5	64/none	RE; 24 x 11/none LE; 24 x 11/none	20/40 20/40	20/25 20/25	+3/+3 +3/+3	0/0 0/0
#6	None/none	RE; 8 x 11/none LE; 2 x 11/none	20/32 20/25	20/25 20/25	+2/+2 +1/+2	0/0 0/0
#7	None/none	24 x 11/ none	20/800	20/32	+4/+4	0/0
#8	80/none	24 x 11/none	20/200	20/25	+4/+4	0/0
#9	None/none	8 x 11/none	20/32	20/20	+2/+2	0/0
#10	48/none	24 x 11/none	20/125	20/25	+3/+4	0/0
#11	64/8	24 x 11/none	20/100	20/40	+3/+3	+1/0
#12[a]	80/8	24 x 11/none	20/125	20/32	+4/+4	+1/0

Abbreviations: ACC, anterior chamber cells; ACF, anterior chamber flare; BCVA, best corrected visual acuity; LE, left eye; RE, right eye.
[a]Subtenon triamcinolone acetonide (40 mg/1 mL) injection was implemented to these patients because of severe clinical course of uveitis.

Safety

- One patient developed malign hypertension after the second dose of SIMPONI, treatment was stopped, and the patient was excluded from the study. There were no reported ocular side effects of SIMPONI.

Fabiani et al (2019)[6] retrospectively evaluated the efficacy of SIMPONI in the management of Behcet's disease (BD)-related uveitis.

Study Design/Methods

- Medical charts from 5 patients (8 eyes) receiving SIMPONI for BD-related uveitis with at least 2 recent relapses (<12 months) of ocular inflammation and resistant to conventional therapy were retrospectively collected.
- SIMPONI SC was administered 50 mg every 4 weeks.
- Previous treatments included systemic glucocorticoids, conventional DMARDs, and biologic agents.
- The endpoints of the study were reduction of ocular flares during the 12 months of treatment with SIMPONI compared to the 12 months preceding therapy with SIMPONI, no change or improvement of BCVA at the 12-months follow-up and reduction in the occurrence of RV assessed by fluorescein angiography (FA) at the 3 and 12 months visit and improvement of the BD Current Activity Form (BDCAF) at the 3- and 12-month follow-up.

Results

Patient Characteristics

- Uveitis was posterior in 1 eye, anterior in 1 eye and 3 patients had bilateral panuveitis (6 eyes).
- No patients received SIMPONI as a first-line biologic therapy and 3 patients received concomitant DMARDs (MTX [n=1], AZA [n=2]).

Efficacy

- The number of flares 12 months before and after receiving SIMPONI decreased from 11 to 1.
- Seven out of 8 eyes (87.5%) had complete control of intraocular inflammation at the 12-month follow-up.
- At the 3 month follow-up, patients with active RV at baseline showed a resolution of RV in 4/4 eyes when assessed by FA.
- The mean BCVA was 6.93±4.34 at baseline and 7.32±3.87 after 12 months of follow-up; the mean BDCAF was 7±2.44 at baseline, 5.4±1.67 at 3 months of follow-up, and 4.2±1.78 at the end of the study.

Safety

- Treatment with SIMPONI was reported as well-tolerated and no adverse events occurred.

Miserocchi et al (2013)[7] conducted a retrospective analysis to assess the efficacy and safety of SIMPONI in 6 patients with JIA and 4 patients with HLA-B27 associated uveitis refractory to previous anti-TNF therapy or other biologic agents.

Study Design/Methods

- Eligible patients had to have an inadequate uveitis and/or arthritis response to 1 or more anti-TNF agents (infliximab, etanercept, or adalimumab) or other non-TNF biologics (rituximab or abatacept).
- Patients received SIMPONI 50 mg once monthly from March 2011 to March 2012.
- The following data were gathered: age, gender, age at onset of uveitis and arthritis, ocular complications, JIA category (International League of Associations for Rheumatology [ILAR] classification), previous therapies (systemic immunosuppressant/corticosteroid), and follow-up.
- The primary endpoint measures were as follows: response to treatment (decrease in uveitis activity), VA improvement, decrease in systemic corticosteroid use, and safety.
- Disease activity was measured according to the SUN criteria.

Results

Patient Characteristics

- A total of 10 patients were included in the study (5 females; 5 males; 20 affected eyes). Six of the 10 patients were treated for active uveitis (B27 group). The remaining 4 patients were treated for active uveitis and arthritis (JIA group). The mean age of these patients was 34.2 years and the mean age at onset of uveitis was 5.1 and 27 years in the JIA and the B27 groups, respectively.
- The mean duration of ocular disease was 21.3 years and all patients had bilateral uveitis (4 anterior, 7 panuveitis). Ocular complications prior to SIMPONI therapy included macular edema (6 eyes), cataract (6 eyes), and glaucoma (4 eyes).
- Patients were followed for an average of 8.2 months.

Efficacy

- Following treatment with SIMPONI, VA remained stable in 15 eyes, improved in 4 eyes, and worsened in 1 eye.
- Three months after starting SIMPONI, cataract extraction was performed in 2 patients. One of these patients had severe macular edema and vision loss after surgical intervention. This patient was treated with periocular corticosteroid injections.
- The mean uveitis activity before treatment with SIMPONI and at the end of follow-up was 2 cells and 0.5 cells, respectively.
- The mean systemic prednisolone dose was reduced from 13.75 mg/day at the start of treatment to 6 mg/day after treatment. A total of 7 patients were receiving low doses of systemic prednisolone (5-12.5 mg daily) at the end of follow-up.
- Four patients were also receiving MTX at the end of follow-up.
- At the final visit, uveitis was inactive in the majority of patients (n=8). The 2 patients who underwent cataract extraction continued to have active uveitis.
- Uveitis activity improved at approximately 2 weeks after the first SIMPONI dose. Additionally, a rapid reduction in ACC was noted.

Safety

- No serious adverse events were reported during the study.

Retrospective Case Series

Cordero-Coma et al (2014)[8] evaluated the short-term safety and efficacy of SIMPONI for the treatment of active immune-mediated uveitis refractory to at least 2 prior immunosuppressive therapies in a nonrandomized, retrospective, interventional case series.

Study Design/Methods

- Thirteen patients with uveitis of different etiologies, who were resistant to local and systemic corticosteroids and at least 1 additional immunosuppressive agent, and who were treated with SIMPONI 50 mg SC every 4 weeks for at least 6 months, were included in this study.
- All patients had an associated systemic immune-mediated disease (JIA [n=4], PsA [n=2], sarcoidosis [n=2], axial spondyloarthropathy [n=2], Behçet [n=2], Vogt-Koyanagi Harada syndrome [n=1]).
- SIMPONI was used as first-line biologic therapy in 1 patient. The other 12 patients received previous treatment with at least 1 other biologic agent (SIMPONI was at least the second biologic agent used).
- In 6 of 13 patients, SIMPONI was used as the only immunomodulatory agent during the study period. Seven patients continued receiving their previous immunosuppressive agents without any modifications in dose (ie, MTX, AZA, mycophenolate mofetil, leflunomide).

- Three patients used topical steroids which were slowly tapered and eventually discontinued after 1 month.
- In all patients, clinical evaluation of uveitis was performed at least 4 times: before treatment, and at 1, 3, and 6 months after initiation of SIMPONI. Clinical evaluation included ophthalmic examination and BCVA.
- Treatment-related adverse events were assessed on each visit.

Results

- A total of 8 men and 5 women (22 affected eyes) with a median age of 30 years were included in the study.
- Twelve out of 13 patients (92.3%) receiving SIMPONI achieved complete control of inflammation, defined as grade 0 cells in both anterior and posterior segments in addition to absence of other signs of intraocular inflammation (cystoid macular edema and vasculitis), after 6 months of treatment.
- Mean BCVA increased from 0.60 at baseline to 0.68 after 6 months of therapy (P=0.009).
- Twelve of 13 patients showed an anterior chamber and/or vitreous inflammation score of 0 at 6 months.
- Mean 1 mm central retinal thickness decreased from a baseline value of 317 to 261.2 µ after 6 months (P=0.05).
- No major systemic side effects associated with SIMPONI were observed. A mild and local cutaneous reaction was recorded in 2 patients.

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, and DERWENT® (and/or other resources, including internal/external databases) was conducted on 11 January 2025. Summarized in this response are relevant data from open-label studies, retrospective studies, and a retrospective case series.

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