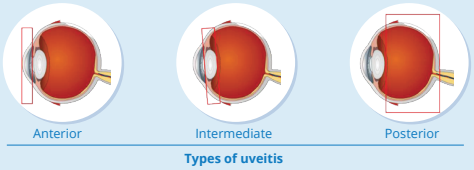
A prospective, real-world, French post-reimbursement study (LOUVRE 2) confirms efficacy of the dexamethasone 0.7 mg intravitreal implant (DEX) in treating the most vision-threatening form of uveitis

Adis OPEN ACCESS PEER-REVIEWED FEATURE

BACKGROUND

Posterior uveitis is the most vision-threatening and challenging form of uveitis to treat, in part due to the target tissue location (back of the eye) and lack of effective topical treatment delivery



OBJECTIVE

To evaluate real-life

- **efficacy,**
- **safety,** and
- **treatment patterns**

with DEX in a population of adults with posterior segment inflammation due to non-infectious uveitis that was treatment-naïve or not

STUDY DESIGN

Prospective, multicenter, non-comparative, post-reimbursement, real-world study

Patients who received DEX treatment on day 0 were followed

(20 representative metropolitan sites)

TREATMENT

Treatment selection decisions (including type and frequency) were made at the investigators' discretion

In cases of bilateral treatment, the eye with the worse best-corrected visual acuity (BCVA) and/or vitreous haze score at enrollment was the study eye

FINDINGS

Enrolled patients (N=245)

Treated with DEX on day 0 before DEX recall[a] (N=97)
Included in all analyses

Completed the following visits pre-recall:[a]
Month 2 (n=91)
Month 6 (n=76)
Month 18 (n=12)

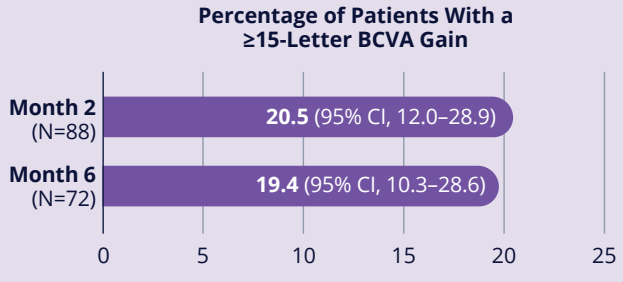
Not treated with DEX on day 0 (n=144)
Analyzed for safety and baseline characteristics

Enrolled after DEX recall[a] (n=4)
Analyzed for safety only

[a]Specific DEX lots were recalled on October 4, 2018, which led to early termination of the study

[b]60 patients treated with DEX on day 0 discontinued the study due to: early study termination following DEX recall (n=55); lost to follow-up (n=2); and other (n=3)

Compared with baseline, statistically significant proportions of patients treated with DEX on day 0 gained ≥15 letters in BCVA at months 2 and 6

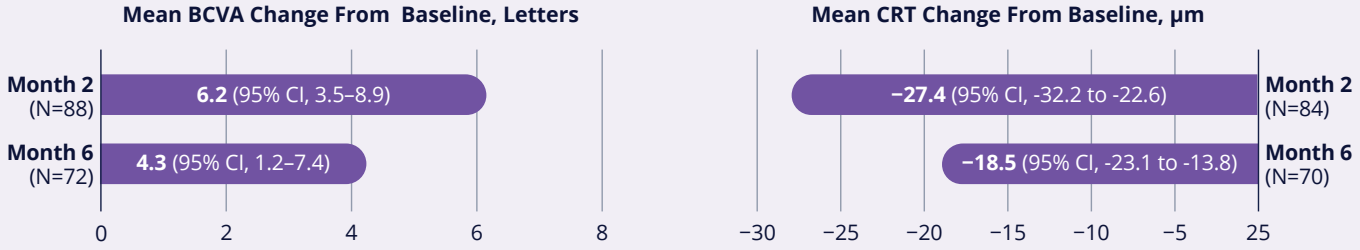


Mean follow-up:
14.9 months

Mean injection interval:
5.1 months

Mean injection number:
1.0

Statistically significant changes in BCVA and CRT from baseline were observed at months 2 and 6



Among patients treated with DEX on day 0, 84 AEs were reported during follow-up; 3 patients discontinued the study due to AEs

Potentially DEX related
32
(38.1%)

Not serious
80
(95.2%)

Not DEX related
52
(61.9%)

Serious
4
(4.8%)

AEs reported in the study (probably/possibly due to the injection procedure or implant, or with uncertain causality)

	Adverse events, n
Total	**32[a]**
Ocular conditions	27
Ocular hypertension	20
Conjunctive hemorrhage	3
Vitreous hemorrhage	2
Cataract	1
Macular fibrosis	1
Medical and surgical procedures	4
Cataract surgery	4
General and administrative site complications	1
Pain at the injection site	1

[a]All occured in patients treated with DEX on day 0

There were statistically significant differences in baseline characteristics between patients treated with DEX on day 0 and those not treated with DEX on day 0

Baseline Characteristics	Treated with DEX on day 0	Not treated with DEX on day 0
Mean CRT, µm (95% CI)	424.8 (397.2, 452,3)	333.6 (313.6, 353.6)
Macular edema present, % (95% CI)	70.2 (61.0, 79.5)	44.0 (35.8, 52.2)
History of cataract, % (95% CI) (surgically operated or not)	76.3 (67.8, 84.8)	56.3 (48.1, 64.4)
Presence of ophthalmic comorbidities, % (95% CI)	88.7 (82.3, 95.0)	70.8 (63.4, 78.3)
Mean age, y (95% CI)	60.6 (57.7, 63.4)	52.7 (49.9, 55.6)
DEX-naïve, % (95% CI)	25.3 (16.5, 34.0)	58.5 (50.3, 66.6)
Prior DEX treatment, % (95% CI)	54.7 (44.7, 64.7)	21.8 (15.0, 28.6)

CONCLUSIONS

In French clinical settings, DEX improved functional and anatomic outcomes with acceptable safety through month 6 in patients with inflammation of the posterior segment due to non-infectious uveitis (including those previously treated with DEX) for whom treatment options remain limited

The sample size was smaller than planned due to the product recall/study termination and difficulty in recruiting patients with this disease of low prevalence/incidence

63.9% of patients treated with DEX received concomitant treatment for uveitis; the observed results could thus be due to combined treatments, as opposed to DEX alone