tech bulletin

Clinical Study Assessing the Tolerance of Spryng™ Administration in Dogs

KEY POINTS

- A clinical study investigated the tolerance and safety of Spryng™ when injected into multiple joints of dogs.[1]
- 20 healthy beagles received intra-articular (IA) injection with saline or Spryng in stifle or elbow joints, followed 2 weeks later by similar IA applications in shoulder or hip joints (total 40 joints each for Spryng or control).
- No differences in incidences of lameness, joint swelling, or pain were detected between joints administered Spryng vs those given saline.
- Spryng is safe for IA injection in dogs.
- Spryng is a Veterinary Medical Device.

EXPERIMENT DESIGN

A clinical study investigated the safety of Spryng,™ a collagen-elastin hydrogel microparticles biomaterial used for the management of osteoarthritis, lameness, and joint pain in dogs.[1] Spryng is a veterinary medical device that does not rely on chemical or metabolic action in the animal's body to achieve intended effect. The study involved 20 healthy beagle dogs, 9 females and 11 males (20-26 lb, ~1.5-4 years of age) with normal baselines for clinical chemistry and joint status (Figure 1). Animals were randomly assigned to 2 groups (group A: n=10, 5 females/5 males; group B: n=10, 4 females/6 males). On study day 0, group A and B animals received an intra-articular (IA) injection of Spryng in a *stifle* or *elbow* joint, respectively, while the opposite stifle or elbow joint of each animal was injected IA with phosphate-buffered saline (control) in a randomized sequence. Pain assessments following the IA injections were performed every 6 to 8 hours for the first day, and dogs were observed daily thereafter for any adverse events. Lameness scoring, joint swelling scoring, and circumference measurements of the stifle and elbow joints were conducted on days 1, 7, and 14, and blood samples were again collected on day 14.

The entire process was repeated using the same dogs beginning on day 15, but with group A and B animals this time receiving IA injections in *shoulder* or *hip* joints, respectively. Thus, data collections during this phase were performed on study days 16, 22, and 29 (again representing 1, 7, and 14 days post-injection). Across the 2 study phases, a total of 40 joints were injected with saline and 40 joints were injected with Spryng.

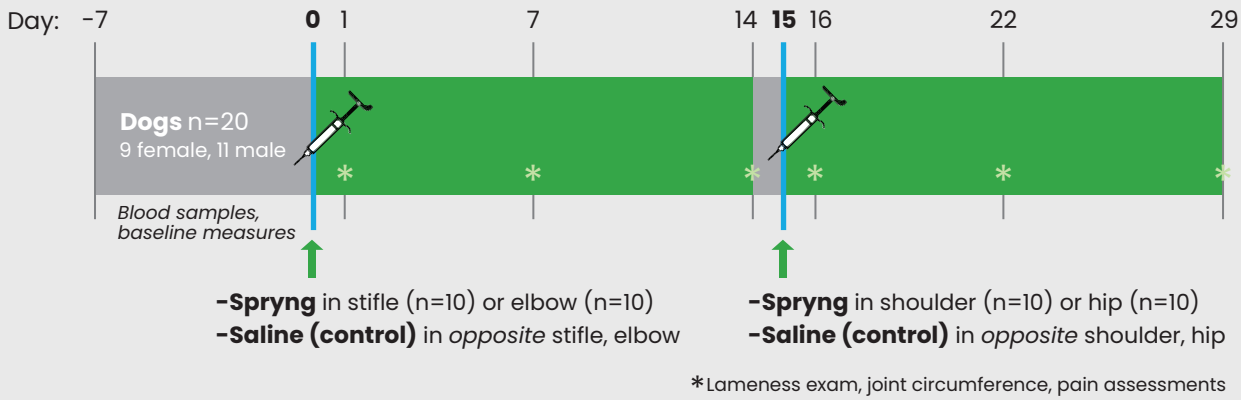

FIGURE 1: Experiment design summary and time line.

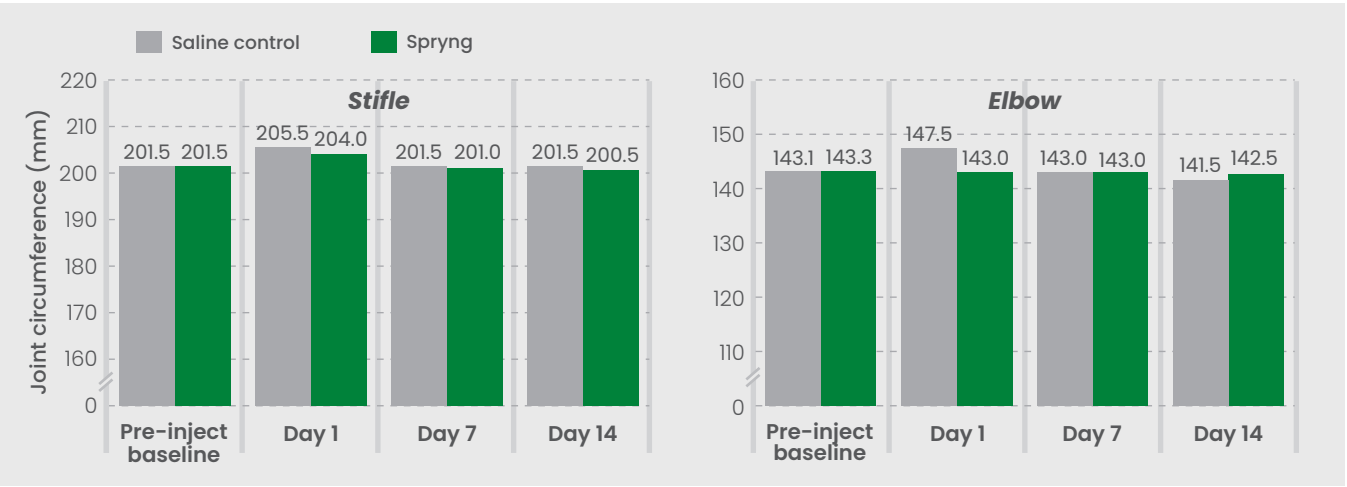

FIGURE 2: Minimal changes in **joint circumference** from pre-injection baseline status after IA injection with saline (control) or Spryng in stifle or elbow joints of dogs.

RESULTS

Results summarized in Figure 2 confirmed that circumferences of joints injected with Spryng were similar to or less than those of control joints injected with saline, and were little changed from baseline measures. Stifle measurements at day 1 post-injection were slightly elevated relative to baseline values for both treatment groups (more so in controls), but circumferences returned to baseline levels by day 7 onward. Similar results were observed for elbow joints, except only control joints demonstrated swelling at day 1 while Spryng joints were unchanged vs baseline. IA injection of Spryng did not contribute to substantial increases in joint circumference (swelling), suggesting little or no reactivity of joint tissues as a result of Spryng administration.

A summary of the 7 categories scored for lameness, swelling, and pain for all 4 joint locations used in the study (Table 1) again confirmed the lack of adverse events associated with application of Spryng. Control dogs averaged higher cumulative adverse scores at day 1 post-injection in stifle (1.1) and elbow (3.4) joints relative to dogs provided Spryng (0.1). (Three of the 20 study dogs presented clinical signs at the day 1 lameness exams, and all these signs resolved by day 4.) Low incidences of adverse scores were detected in shoulder joints for both groups (0.1), and none in hip joints. Scores collected at days 7 and 14 post-injection showed no adverse impacts of Spryng at any of the 4 joint locations. Thus, the toleration and safety of Spryng was again confirmed by the outcomes of these scored assessments.

All other monitored parameters (clinical observations, hematology, blood chemistry, clotting panel) were within normal ranges, were similar between treatment groups.

TABLE 1 – Average sum of all scores for lameness, joint circumference, and pain.

	Stifle	Elbow	Shoulder	Hip
1 day post-injection				
Control	1.1	3.4	0.1	0
Spryng	0.1	0.1	0.1	0
7 days post-injection				
Control	0	0.3	0	0
Spryng	0	0	0	0
14 days post-injection				
Control	0	0	0	0
Spryng	0	0	0	0

CONCLUSIONS

This study demonstrated the excellent safety profile of Spryng when injected IA into 40 joints (10 each, stifle, elbow, shoulder, hip) across 20 individual dogs. Use of Spryng was similar to a benign control (saline) in regard to incidences of lameness, joint swelling, or pain after IA injection, and post-injection outcomes were most often no different than pre-injection baseline measures.

REFERENCES

1. Data on file, PetVivo, Inc. (in press)

PetVivo, Inc.