tech bulletin

Clinical Study Assessing the Tolerance of Spryng™ Administration in Cats

KEY POINTS

- A clinical study investigated the tolerance and safety of Spryng™ when injected into multiple joints of cats.[1]
- 10 healthy female cats received intra-articular (IA) injection with saline or Spryng in contralateral shoulder, hip, elbow, and stifle joints in a randomized sequence. A 2-week washout period transpired between each target joint injection (total 40 joints each for Spryng and 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 cats.

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 cats.[1] The study involved 10 healthy female cats (5-6.6 lb, 8-9 months of age) with normal baselines for clinical chemistry and joint status. The trial consisted of 4 sequential, nearly identical 14-day phases, each involving a different joint (Figure 1). On study day 0, animals had a shoulder joint injected IA with Spryng while the opposite shoulder joint of each animal was injected with phosphate-buffered saline (control) in a randomized sequence. Fifteen days later, the same cats received IA injections in hip joints, followed by elbow injections at day 30. For the last phase (stifle), injection was 18 days after the previous injection because of the weekend schedule. Thus, injections for each joint location were initiated on days 0, 15, 30, and 48, with each new phase initiated only if cats returned to baseline status for all study parameters.

Pain assessments following the IA injections were performed twice daily for 3 days, and cats were observed daily thereafter for any adverse events. Lameness scoring and joint swelling scoring (and circumference measurements for elbow and stifle joints) were conducted on days 1, 7, and 14 after each

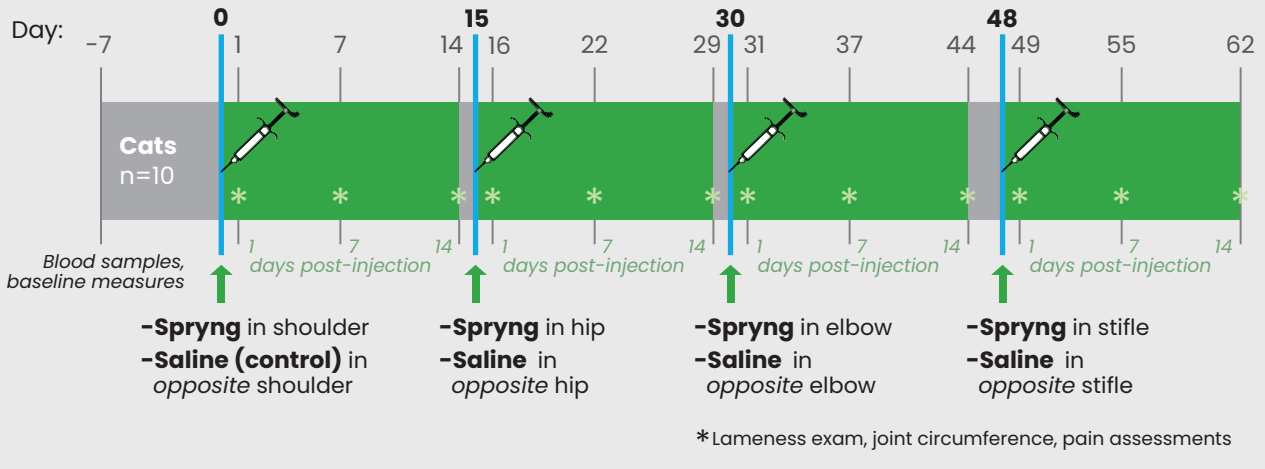

FIGURE 1: Experiment design summary and time line.

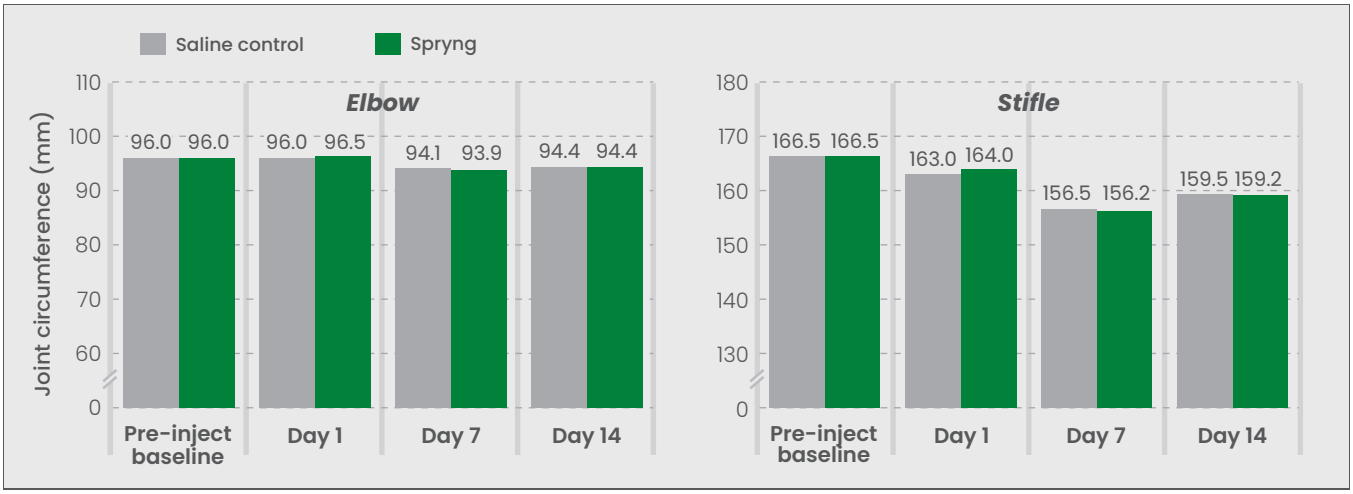

FIGURE 2: Minimal changes in **joint circumference** from pre-injection baseline status after IA injection with saline (control) or Spryng in elbow or stifle joints of cats.

injection. Blood samples were again collected 14 days following the 2nd and last injections (days 29 and 62).

Across the 4 study phases, a total of 40 joints were injected with saline and 40 joints were injected with Spryng.

RESULTS

Results summarized in Figure 2 confirmed that circumferences of joints injected with Spryng were similar to (or often less than) those of control joints injected with saline. Further, injected joints were little changed from baseline measures (except for the favorable reduction of joint circumferences at days 7 and 14 post-injection), demonstrating the lack of swelling due to IA injections with Spryng in elbow and stifle joints. Clearly, IA injection of Spryng did not cause substantial increases in joint circumference (swelling), so Spryng contributed little or no reactivity to joint tissues.

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. Only extremely low incidences of clinically insignificant adverse scores were detected in hip and elbow joints for both groups (≤0.4 on day 7, out of 20 as the worst possible score), and none in shoulder joints. Most pain assessments and clinical observations were devoid of clinical signs by the day following each injection. 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 groups, and remained similar between pre-injection baseline and post-injection assessments. No cats became ill or died during the course of the study.

TABLE 1 – Avg. sum of all scores for lameness, joint swelling, and pain (worst possible score=20).

	Shoulder	Hip	Elbow	Stifle
1 day post-injection				
Control	0	0.2	0	0
Spryng	0	0.2	0.1	0
7 days post-injection				
Control	0	0.4	0.2	0
Spryng	0	0.4	0.2	0
14 days post-injection				
Control	0	0.2	0	0
Spryng	0	0.2	0	0.1

CONCLUSIONS

This study demonstrated the excellent safety profile of Spryng when injected IA into 40 joints (10 each, shoulder, hip, elbow, stifle) across 10 individual cats. 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.