ARRIVE Essential 10 Checklist

1. Study design

This was an acute in vivo preclinical study involving two adult female sheep (Ile-de-France breed) to evaluate a handheld neurosurgical robot. No control group was used. The study employed multiple surgical approaches (subfrontal, transparietal, supracerebellar) to assess three robotic instruments. Each animal underwent a terminal procedure followed by euthanasia.

2. Sample size

Two sheep were included in the study. No formal sample size calculation was performed as this was an exploratory IDEAL Stage 0 feasibility study to evaluate device usability and safety.

3. Inclusion and exclusion criteria

Animals were selected based on weight (82.5–86.0 kg) and age (38–44 months). No imaging or disease-based inclusion/exclusion criteria were applied.

4. Randomisation

No randomisation was used as each animal received all procedures and instruments.

5. Blinding

Blinding was not employed due to the exploratory and technical nature of the surgical evaluation.

6. Outcome measures

Feasibility was measured by task completion scores using a 4-point Likert scale (1 = very easy to 4 = impossible). Safety was assessed by intraoperative monitoring and macroscopic necropsy.

7. Statistical methods

Descriptive statistics (mean scores) were used. No inferential statistics were applied.

8. Experimental animals

Two female Ile-de-France sheep aged 38–44 months. Animals were sourced from an approved provider and acclimated for 7 days pre-procedure.

9. Experimental procedures

Animals underwent craniotomy and neurosurgical simulation under general anesthesia. Premedication: morphine (0.23–0.24 mg/kg IM), midazolam (0.52–0.55 mg/kg IM). Induction: midazolam (0.46–0.48 mg/kg IV), propofol (1.8–2.09 mg/kg IV). Maintenance: propofol (13.9–20 mg/kg/h IV), sufentanil (3–5 µg/kg/h), midazolam (0.3–0.5 mg/kg/h IV),

isoflurane (2%) in one animal. Euthanasia: heparin (2 mg/kg IV), then pentobarbital (91 mg/kg IV).

10. Results

All tasks were feasible with no major complications. All predefined tasks were completed; no adverse events occurred. Necropsy revealed only mild hemorrhages related to surgical access, not the device.