Viroplazin Clinical Trial Protocol for Dogs and Cats

Study Overview
This proposed multicenter, randomized, double-blind, placebo-controlled clinical trial is designed to evaluate the efficacy and safety of Viroplazin in dogs and cats with selected viral diseases. Viroplazin will be compared with a matched placebo. Animals in both groups will receive appropriate standard veterinary care for their condition.

Viral Diseases Included

Dogs
- Parvovirus gastroenteritis
- Canine distemper

Cats
- Feline viral rhinotracheitis
- Feline calicivirus infection
- Feline panleukopenia

Study Objective
The study aims to determine whether Viroplazin, administered alongside standard veterinary care, improves clinical recovery and viral clearance compared with placebo and standard care. Safety will be evaluated through adverse-event monitoring and laboratory testing.

Study Design
The trial will use a parallel-group design with two treatment arms:
- **Viroplazin group:** Viroplazin plus standard veterinary care.
- **Placebo group:** A matched placebo plus standard veterinary care.

Eligible animals will be randomly assigned to either group in a 1:1 ratio. Owners, treating veterinarians, and designated study staff will remain blinded to treatment allocation. Randomization will account for disease type and baseline severity to support comparable treatment groups.

Eligibility Criteria

Inclusion Criteria
Animals must meet all of the following criteria:
- Be older than three weeks.
- Have a confirmed diagnosis of one of the included viral diseases, based on PCR or an appropriate antigen test.
- Show clinical signs consistent with the diagnosis.
- Have written informed consent from their owner.

Animals of either sex and any breed may be eligible.

Exclusion Criteria
Animals will be excluded if they have:

- Severe concurrent illness, such as significant kidney or liver dysfunction or an uncontrolled bacterial or parasitic infection.
- Received antiviral or immune-modulating treatment within seven days before enrollment.
- A known hypersensitivity to any Viroplazin ingredient.

Pregnant or lactating animals will also be excluded.

Treatment and Supportive Care

Investigational Treatment
The proposed study regimen is oral administration of Viroplazin at **5 mg/kg of body weight, three times daily for seven consecutive days**.
The placebo will be visually matched and administered using the same schedule.
This regimen is part of the proposed clinical trial protocol and is not general treatment guidance.

Standard Veterinary Care
Animals in both groups will receive appropriate supportive care based on their clinical needs. This may include:

- Intravenous fluids for dehydration.
- Antiemetics for vomiting.
- Oxygen support when clinically indicated.
- Pain and fever management.
- Other treatments considered necessary by the treating veterinarian.

Supportive care will be documented for each animal.

Clinical Assessments and Data Collection
Electronic case report forms (eCRFs) will be used to collect standardized clinical information. Before treatment begins, investigators will record:

- Confirmed diagnosis.
- Baseline clinical severity.
- Duration of illness before enrollment.
- Relevant medical history.
- Diagnostic and laboratory results.

Clinical signs will be assessed daily from Day 1 through Day 7. Follow-up will continue through Day 14.

Disease-Specific Assessments

Disease	Clinical signs and findings recorded
Canine parvovirus gastroenteritis	Fever, vomiting and diarrhea frequency, blood in feces, appetite, hydration, and activity level

Canine distemper	Fever, respiratory signs, neurological signs, gastrointestinal signs, ocular discharge, and activity level
Feline viral rhinotracheitis	Sneezing frequency, ocular discharge, nasal discharge severity, fever, appetite, hydration, and activity level
Feline calicivirus infection	Oral ulcers, drooling, respiratory signs, fever, appetite, and activity level
Feline panleukopenia	Fever, vomiting and diarrhea frequency, blood in feces, leukopenia, hydration, and activity level

Proposed Clinical Scoring Scale
The draft protocol uses the following categories:

Score	Classification
0	No clinical signs
1	Mild
2	Moderate
3	Severe
4	Very severe
5	Critical
6	Death

Disease-specific scoring definitions and the method for calculating overall severity must be finalized before enrollment begins.

Outcome Measures

Primary Efficacy Outcomes
- Change in disease-specific clinical scores from Day 1 to Day 7.
- Viral clearance, assessed using PCR or appropriate antigen testing on Days 4 and 7.

Secondary Efficacy Outcomes
- Time to clinical improvement, defined in the draft protocol as a reduction of at least 50% in the primary clinical signs.
- Time to resolution of clinical signs.
- Mortality through Day 14.
- Recurrence or worsening of symptoms during the 14-day observation period.

Safety Outcomes

- Frequency, severity, and description of adverse events.
- Changes in hematological and biochemical parameters from baseline to Days 7 and 14.
- Treatment discontinuation due to adverse events.

Planned Enrollment

The draft proposes **100 animals per disease**, with 50 assigned to Viroplazin and 50 assigned to placebo.

If this target applies to each of the five listed diseases, total planned enrollment would be **500 animals: 200 dogs and 300 cats**.

The final enrollment target and statistical power calculation must be confirmed before the protocol is finalized.

Statistical Analysis

The planned analysis includes:

- Intention-to-treat and per-protocol analyses.
- Chi-square or Fisher's exact tests for appropriate categorical outcomes.
- Kaplan–Meier analysis for time-to-event outcomes.
- Descriptive analysis of safety findings.

The final statistical analysis plan will specify methods for clinical scores, disease-specific comparisons, missing data, and treatment withdrawals.

Data Management and Study Documentation

Study data will be recorded in standardized eCRFs. Monitoring will assess protocol adherence, completeness of records, and data accuracy.

Documentation will include:

- Patient identification and medical records.
- Baseline and follow-up clinical scores.
- Diagnostic and laboratory reports.
- Treatment and supportive-care records.
- Adverse events and withdrawal details.
- Photographs or video recordings, where appropriate and covered by owner consent.

Any material intended for public use will require appropriate consent and protection of identifying information.

Ethical Oversight and Animal Welfare

The study is intended to follow applicable veterinary research requirements and Good Clinical Practice principles.

Before enrollment begins, the study team must confirm and document:

- Approval from the relevant institutional ethics committee.
- Written informed consent from owners.
- Appropriate investigator training.
- Standard-of-care requirements for both treatment groups.
- Withdrawal criteria and follow-up care arrangements.

Necessary veterinary care will be provided throughout the study.

Study Timeline
Each enrolled animal will receive seven days of investigational treatment, with follow-up continuing through Day 14.
Recruitment is expected to take approximately **3–12 months**, depending on eligible case availability. The overall study timeline will be finalized to account for recruitment, follow-up, data analysis, and reporting.

Reporting
Baseline and end-of-treatment records will document each animal's clinical status and outcomes. Deaths, adverse events, and treatment withdrawals will also be recorded.
An interim analysis is proposed after 50% of the planned enrollment has been reached.
Final reporting will summarize clinical outcomes, viral testing results, safety findings, and study limitations.

This document describes a proposed clinical study. It does not report completed trial results or establish the efficacy or safety of Viroplazin.