

Two clinical studies to evaluate the efficacy of a novel subunit vaccine in the reduction of clinical signs (i.e. diarrhea) caused by *C. parvum* infections in neonatal calves

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INTRODUCTION

Neonatal Calf Diarrhea (NCD) leads to calf mortality worldwide. *Cryptosporidium parvum* causes a large proportion of NCD cases. The discovery of a glycopeptide epitope on *Cryptosporidium* parasites has led to the development of a Gp40 subunit vaccine (Bhalchandra, 2023). Vaccination of pregnant cows and heifers reduces clinical signs (diarrhea) in their calves via passive immunization through colostrum (Timmermans, 2024).

OBJECTIVE

Two multisite, randomized, negative controlled and double-blind GCP clinical studies were conducted on commercial farms in the Netherlands and France to evaluate the efficacy of this vaccine in dairy and suckling calves. The purpose of these studies was to detect reduction of the incidence, severity, and duration of diarrhea in calves having ingested colostrum from vaccinated dams.

MATERIALS AND METHODS

The animals vaccinated in these studies were healthy cows and heifers between 10 and 6 weeks before the expected date of calving. Study treatment consisted of subcutaneous application of one dose of Bovilis® Cryptium® for the test group, and saline solution in the control group (1:1). This treatment was repeated 4 weeks later. In the calves born from study dams, the scores for general health (0 = healthy, 3 = moribund), feed intake (0 = Drinking, 2 = not drinking) and fecal consistency (Fc)* (0 = normal, 3 = watery) and number of treatments against diarrhea were compared between study groups. To assess these parameters, all calves were assessed and scored daily during 21 days after birth. To confirm the antibody response to vaccination, colostrum samples were tested for antibodies against the Gp40 protein. Passive transfer of these antibodies was tested by analysing calves' serum after colostrum intake, and treatments were registered.

* Modified Wisconsin-Madison

The newly developed Gp40 vaccine is efficacious in mitigating the impact of *C. parvum* caused diarrhea in neonatal calves.



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RESULTS

The protective effect of vaccination was shown in the odds ratios for the efficacy parameters in both independent studies. These were in favour of the calves from vaccinated dams. Also, in both studies the levels of antibodies against Gp40 were markedly higher in colostrum as well as calves' serum in the vaccinated groups compared to the control groups. In suckling calves, the incidence of diarrhea cases was too low to demonstrate reduction of duration, but the average duration of the diarrhea episodes in dairy calves was significantly reduced from 2.2 days in the control group to 1.6 days in the vaccinated dam's group (Mixed model ANOVA p=0.0300).

FIGURE 1-2. Odds ratios for clinical parameters in calves from vaccinated dams; lower chances of clinical observations related to diarrhea; left: dairy, right: suckling calves.

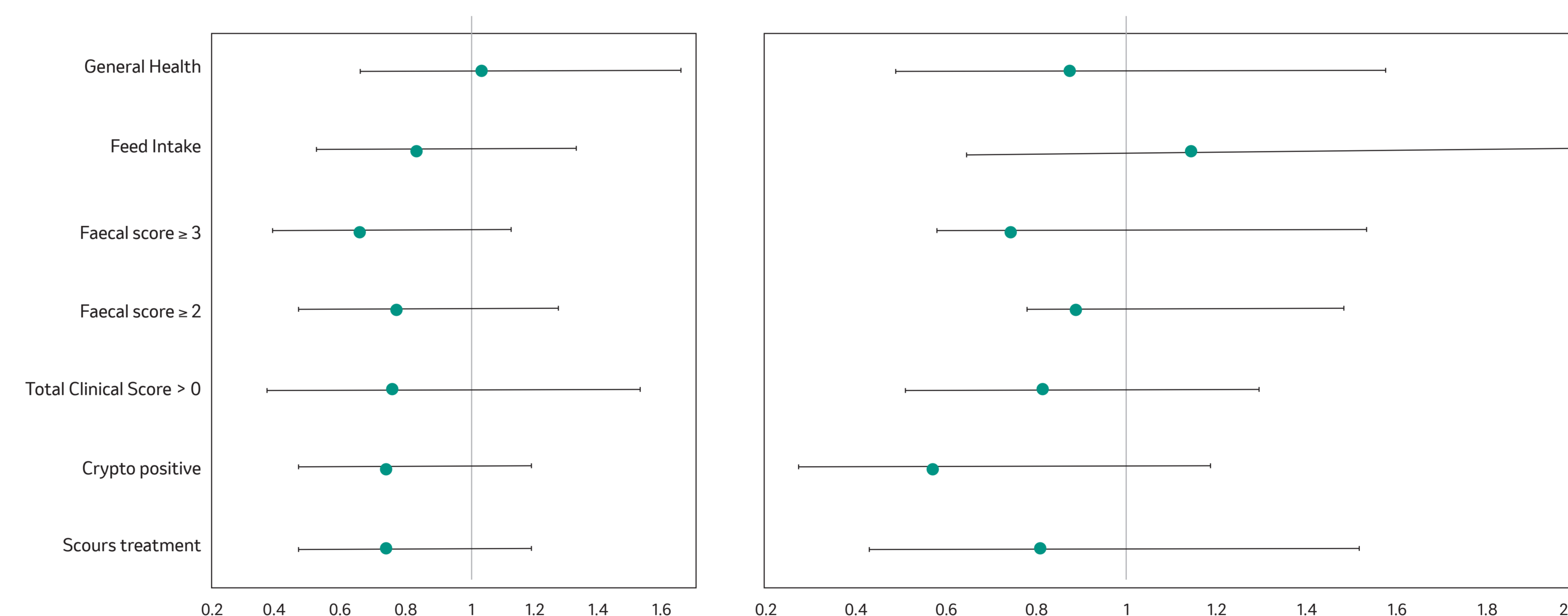
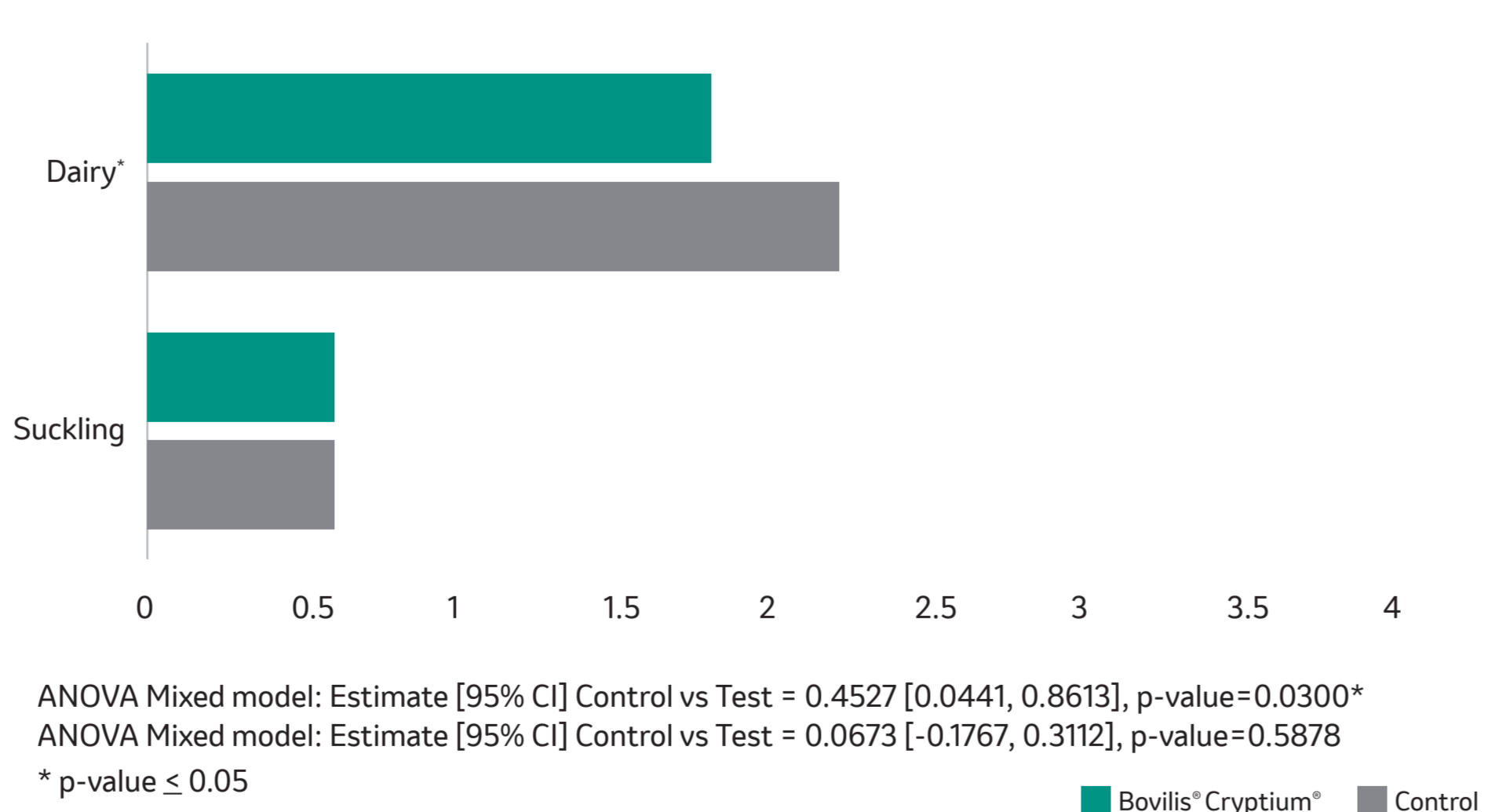
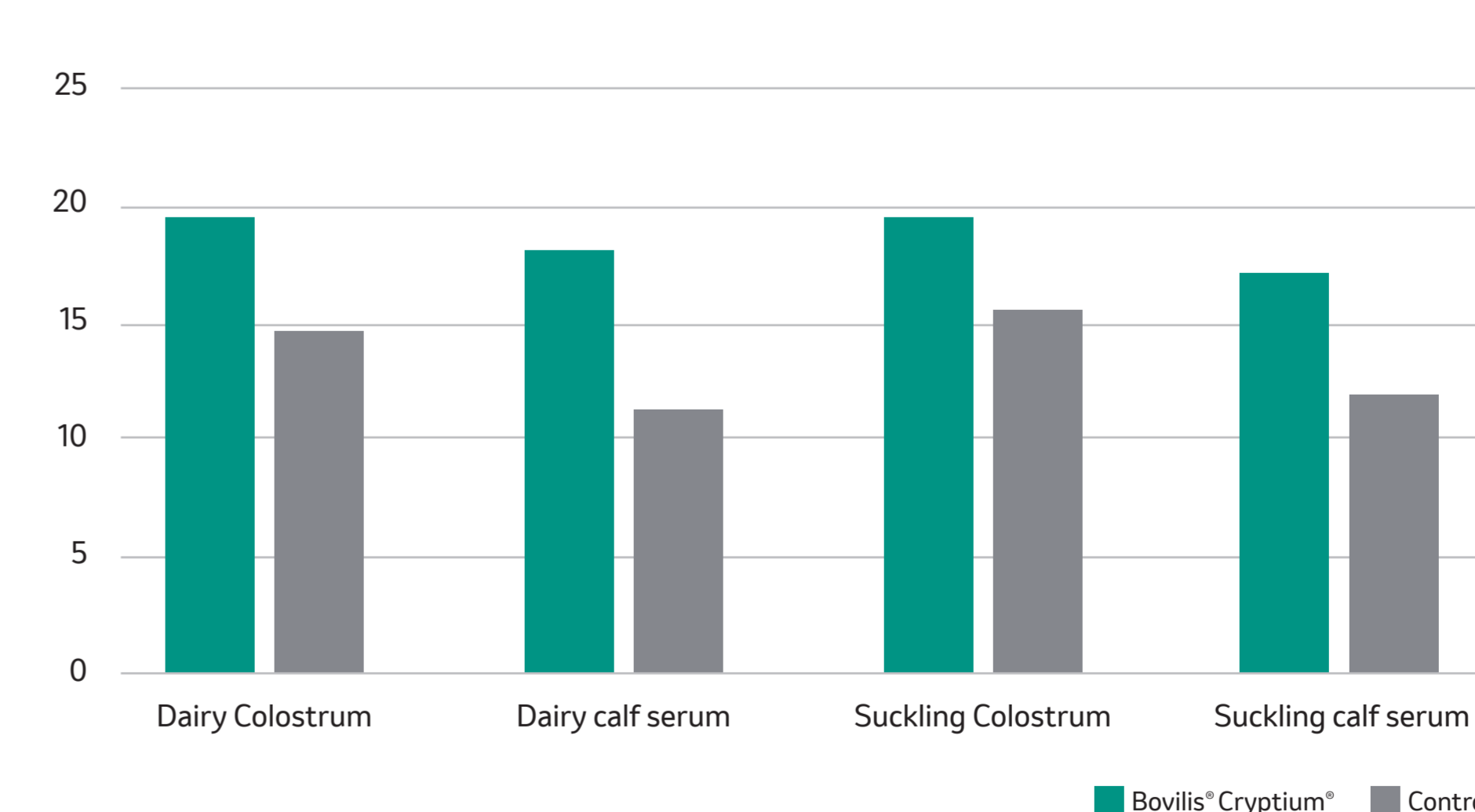


FIGURE 3. The duration of diarrhoea, the mean number of days a calf showed a faecal consistency score ≥ 2 in the test group, compared to the control group.



ANOVA Mixed model: Estimate [95% CI] Control vs Test = 0.4527 [0.0441, 0.8613], p-value=0.0300*
ANOVA Mixed model: Estimate [95% CI] Control vs Test = 0.0673 [-0.1767, 0.3112], p-value=0.5878
* p-value ≤ 0.05

FIGURE 4. Average Log₂ Gp40 antibody titers in colostrum and calf serum with and without vaccination with Bovilis® Cryptium®.



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