

Serum amyloid A in foals with neonatal enterocolitis

Explanation: Serum amyloid A (SAA) is a marker of inflammation and infection in the horse. In the blood of healthy horses, SAA concentration is very low, but it increases dramatically with inflammation or infection. Increased concentration in blood closely reflects the onset of inflammation or infection, often before clinical signs appear, giving the veterinarian an indication to run additional diagnostics and get a jump start on treatment. Once effective treatment is initiated and/or patient's immune system responds, inflammation or infection begins to decrease and SAA levels tend to decrease dramatically as well. More recently SAA has been investigated for aiding in the diagnosis of sepsis (infections) in equine neonates. It was found that septic foals had a significantly greater median SAA concentration compared to sick non-septic and healthy foals. Furthermore, repeat SAA testing over the course of treatment allows the veterinarian to monitor whether the treatment is effective or not.

Purpose: While SAA concentrations have been studied in foals with septicemia (blood infections) and/or local infections compared to healthy foals, there is lacking information for SAA concentrations in foals with diarrheal infections or diarrhea from other causes. Diarrhea is a prevalent issue among foals often necessitating the expertise of a veterinarian for proper management. It can cause numerous secondary complications, including endotoxemia, metabolic issues such as acidosis and hypovolemic shock, and bacteremia and septicemia, especially if associated with an underlying infectious enteritis/enterocolitis.

The purpose of this study is to monitor SAA concentrations in foals with diarrhea compared to septic foals without gastrointestinal (GI) disease or healthy foals.

<u>**Clinical Protocol</u>**: Foals admitted to the Veterinary Health Center, Manhattan, Kansas (KSU) with diarrhea or septic foals without GI symptoms, will have the following procedures/tests done as standard of care for diagnostics and to help determine proper treatment plans: physical examination with vitals, blood drawn for baseline blood work to include CBC, biochemistry, IgG test and blood culture. Fecal sample will be collected for foals with diarrhea and submitted for UC Davis Foal Diarrhea panel and an abdominal ultrasound may be warranted.</u>

For clinical trial purposes, SAA concentrations will be evaluated at the time of admission and every 24 hours until Day 7, until discharge, or until the SAA value is normal (<20 ug/ml), whichever is last.

It is anticipated that SAA concentrations will be:

- Higher in foals with diarrhea than in septic foals without GI disease or healthy foals;
- Higher in foals with poor outcome than in foals with good outcome;
- Increased from Day 0 to Day 1 and from Day 1 to Day 2 will be associated with poor outcome;
- Higher in foals with positive blood cultures than foals with negative blood cultures;
- Higher in foals with diarrhea caused by *Clostridium perfringens* than in foals with Rotavirus.

Investigators:

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Eligibility:

Foals < 1 month old admitted to the Veterinary Health Center, Manhattan, Kansas (KSU) with:

- History of diarrhea within 24 hours of presentation, diarrhea on intake, evidence of diarrhea on their tail/hind end on intake, or develop diarrhea within 12 hours of intake.
- Sepsis (abnormal sepsis score >/= 11) and no signs of gastrointestinal disease.
- For healthy controls, the study will be enrolling apparently healthy foals < 1 month old with normal parameters on physical examination, normal age-appropriate bloodwork (CBC, biochemistry), and normal sepsis scores.

Miniature horses, donkeys and mules will be excluded from the study.

Foals with diarrhea and septic foals without GI disease will be treated appropriately and will have follow up diagnostics performed according to their disease and clinical signs by their attending clinicians.

<u>Risks</u>: For study purposes, the only change to the patient's standard of care and/or treatment plan will include the blood draws for the SAA sampling. When possible, blood will be drawn from an intravenous catheter already placed for treatment purposes. Alternatively, blood will be drawn by venipuncture as deemed appropriate (using a needle and syringe) from a jugular vein and the samples submitted for testing. The risk of venipuncture is low, but may include mild transient discomfort, bruising, redness, swelling, or hematoma formation at the venipuncture site.

If a foal becomes extremely anxious about blood collection they will be removed from further study participation.

<u>Fees for Services</u>: There are no fees associated with participating in this study. Furthermore, there is no direct compensation provided. The study funds will cover all costs associated with blood draws and SAA testing. Owner is responsible for all costs associated with diagnostics, treatment and hospitalization plans as recommended by the attending clinician and which are not part of this study.

<u>**Owner Responsibilities:**</u> You must approve your foal's participation in the study by reviewing and signing a client consent form. At enrollment, owners will be asked to complete a questionnaire regarding health conditions of both the foal and mare including gestation and postpartum situations. Study participation ends at the time of discharge (or death) with the exception of a follow up call 7 days after discharge, when applicable, to determine a longer-term outcome.

For questions or concerns regarding this study, please contact:

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