ULTAMINO™ - CLINICAL TRIALS

THE VETERINARY CLINICS INVOLVED

• This field study was conducted during 2011 in 6 veterinary practices, in France and Spain, in order to validate the efficacy of ULTAMINO™ on dogs suffering from Adverse Food Reaction.
• Veterinarians chosen with a special interest and expertise in dermatology.

TRIAL PROTOCOL

Selection Criteria

• Adult dogs, suffering from Adverse Food Reaction (A.F.R.):
  - Dogs already diagnosed with A.F.R.
  - Or dogs suspected to suffer from A.F.R., according to their history and clinical signs
  - Dogs previously put on a hypoallergenic diet (fig.1)
• With a CADESI© score ≥50, and a pruritus score between 2 and 4
• No concurrent severe pathology
• Not suffering from gastrointestinal inflammation or secondary dermatitis (e.g. pyoderma, Malassezia dermatitis)
• Treated for external parasites >72h and <1 month ago, and for internal parasites >72h and <6 months, at the start of the trial

22 dogs were included in these clinical trials

Various sizes and breeds of dogs
  • Mean weight: 38 lb
  • Mean age at inclusion: 5.9 years old

FIG. 1

Circumstances of inclusion in the trial

Incomplete response to hypoallergenic diets
First elimination diet protocol

Treatments

Authorized Treatments

Antibiotics / antifungals / corticosteroids: as topical treatments, or as short-term oral route treatment.

Prohibited Treatments

• Antibiotic or antifungal treatment by oral route for more than 10 days
• Long-term or extended-action corticosteroids, antihistamines, and immunomodulators
• Dietary supplements for skin disorders

Study Design

• After appropriate dietary transition, the animals were fed exclusively with the test diet (ULTAMINO™) during the elimination diet period.
• Improvement was quickly observed in all dogs. Consequently after 4 weeks, the dietary challenge was performed (back to previous diet), making clinical signs reappear within a week.
• The dogs were then put on the test diet again for 2 months.
• V0, V1, ... , V4: veterinary consultations and evaluations by owners.

Assessment of the Efficacy of the Diet

By the Veterinary Practitioners

At each visit, the investigators were asked to perform a full clinical examination, a specific dermatological examination, and to report data on the case report form.

The dermatological examination included:
• Assessment of a CADESI© score, a pruritus score, and the gold standard evaluation: the Global Skin Score* (GSS)
• Skin cytology with transparent tape test or skin scraping was performed if necessary
• For visits V1 to V4, the investigators were asked to record if the skin lesions had worsened since the last visit
• Photographs of the most important lesions were taken at each visit

By the Dog Owners

Owners evaluated, at each time period, skin condition and pruritus level, and gave their opinion about overall satisfaction. Dog owners were also asked to evaluate the test diet for:
• Digestibility (evaluation by several means, including the use of a fecal score grid (scores from 1 to 5, with 1 being too soft, 5 being too hard, 4 being the optimal level))
• Palatability (scores from 1 to 5, with 1 being the least palatable and 5 being the most palatable)

* CADESI-03© grid *: extract

Global Skin Score: “Evaluation of the pruritus in dogs with atopic dermatitis.” Cordes K, Veterinary1Rese4, 2007-2011

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**TRIAL RESULTS**

**PROGRESSION OF THE MEAN GLOBAL SKIN SCORE (G.S.S.)***

<table>
<thead>
<tr>
<th>V0</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
</tr>
</thead>
<tbody>
<tr>
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<td>2.5</td>
<td>2.3</td>
<td>1.1</td>
<td>0.8</td>
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</tbody>
</table>

**Trial time-points (visits)**

**Dietary challenge**

**5 year old intact male French Bulldog**

**History**

- Adverse Food Reaction and atopic dermatitis highly suspected (elimination diet trial had been previously performed, but not the dietary challenge)
- After this AFR suspicion, the dog was put on a hydrolyzed protein diet. Salami was also prescribed oral corticosteroids in times of pruritic crisis, but not in the inter-crisis periods.
- *0.7 mg/kg/day

**Participation in clinical trial**

- Clinical signs improved upon starting ULTIMINO®. As expected upon dietary challenge, clinical signs reappeared in less than 10 days, thus confirming the diagnosis of AFR.
- With ULTIMINO®: Salami had significant improvement of pruritus, erythema, and lesions, and the corticosteroids were no longer needed.

**The dog owner’s testimonial**

"Before this trial, Salami had been fed with a hydrolyzed protein diet, and he needed some steroids from time to time. But there was still a lot of itching (on his paws), redness of the skin (limbs, abdomen), dull coat with some scales and a lot of dandruff. After 2 months on the test diet (with no more steroids), we could see:
- A decrease in itching and redness of the skin (from red to clear pink)
- No more dandruff

The result is better than on a traditional hydrolyzed diet + steroids. And, coat improvement is very noticeable."

**12.2 year old spayed female Chinese Shar-Pei**

**History: Clinical signs since 10.5 years of age**

**The Veterinarian’s testimonial**

"Measurable improvement with the test diet. Amazing hair growth. And we can pet her again, whereas it was 'cactus-like' before!"

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* Global Skin Score = (CADESI© score x Pruritis Score) / 100

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