Efecto de la suplementación con concentrado de inmunoglobulinas a partir del suero bovino en la Microbiota y su contribución a la salud intestinal y al sistema nervioso central

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The LGI Group serves industrial, veterinary and human applications with high quality, natural source proteins.

<table>
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<tr>
<th>Raw material</th>
<th>Vegetal &amp; Animal Health/Nutrition</th>
<th>Human Nutrition</th>
<th>Pharma/Biologicals/Human health</th>
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<tbody>
<tr>
<td>Blood, Bones, Feather, Fatty tissues</td>
<td>all by-products</td>
<td>Blood</td>
<td>Blood, Skin, Fatty Tissue, Bones</td>
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<tr>
<td>Blood</td>
<td>Dairy</td>
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IBS
• Post-Infectious Diarrhea
• Pediatric IBS-D
• Infant Diarrhea
• Symptom Management
• Small Intestine Bacterial Overgrowth

IBD
• Chron’s Disease
• Ulcerative Colitis
• Pediatric UC
• Pouchitis

IBS
• HIV Enteropathy
• Norovirus and Cryptosporidium
• C. Difficle

Pediatric IBS
• Celiac and Gluten Sensitivity
• Antibiotic Induced Diarrhea
• DMARD-Induced Diarrhea
• Chronic Mesenteric Ischemia
• Lymphocytic Colitis
• Chronic Diarrheal Ileorectal Anastomosis
• Fecal Incontinence
• Mastocytic Enterocolitis
• Short Bowel Syndrome

Cancer Cachexia
• Cancer Associated weight Loss Syndrome
• Gut Barrier Dysfunction and microbial translocation
• Chemotherapy Induced Mucocitis

Specialties Targeted:
• GI Anti-inflammatory
• Hypercholesterolemia
• Microbiome Dysbiosis
• Autism
• Hepatic
• Leaky GUT
• Acid Reflux
• H. Pylori

Other DI
• Leaky GUT
• Acid Reflux
• H. Pylori

Hepatic
• Cancer Cachexia
• Gut Barrier Dysfunction and microbial translocation

Medical Food Product

EnteraGam®
(sera-derived bovine immunoglobulin/protein isolate, SBI)

Prescription Medical Food Product
Dispense by Prescription
Use Under Physician Supervision

EntheaHealth
Results from a 6-week, randomized, double-blind, placebo-controlled study (N = 66). Subjects received either EnteraGam® 10 g daily, 5 g daily, or placebo. Subjects self-assessed presence and severity of GI symptoms daily using a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). Number of days with symptoms was calculated for each 2-week period per subject. Data represents within-group changes from baseline to end of study among: (1) Subjects taking 10 g dose of EnteraGam® daily (n=15); and (2) subjects within say protein placebo group (n=22). No statistically significant reduction in the number of days with any GI-related symptoms for placebo group. Study was not powered to demonstrate between-group differences.

Clinical Medicine Insights: Gastroenterology
Evaluation of Serum-Derived Bovine Immunoglobulin Protein Isolate in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome - 2013:6 49–60.
Dale Wilson, Malkanthi Evans, Eric Weaver, Audrey L. Shaw, Gerald L. Klein
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4020402/

* Results from a 6-week, randomized, double-blind, placebo-controlled study (N = 66). Subjects received either EnteraGam® 10 g daily, 5 g daily, or placebo. Subjects self-assessed presence and severity of GI symptoms daily using a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). Number of days with symptoms was calculated for each 2-week period per subject. Data represents within-group changes from baseline to end of study among: (1) Subjects taking 10 g dose of EnteraGam® daily (n=15); and (2) subjects within say protein placebo group (n=22). No statistically significant reduction in the number of days with any GI-related symptoms for placebo group. Study was not powered to demonstrate between-group differences.
Published Clinical Cases – Irritable Bowel Syndrome w/ Diarrhea (IBS-D)

Case Series of 10 Drug-Refractory IBS Patients Who Respond to Oral Serum-Derived Bovine Immunoglobulin/Protein Isolate (SBI)

Serum-Derived Bovine Immunoglobulin/Protein Isolate Therapy for Patients with Refractory Irritable Bowel Syndrome

Nutritional management with serum-derived bovine immunoglobulin benefits refractory IBS-D patients

For patients with drug-refractory irritable bowel syndrome, nutritional management with serum-derived bovine immunoglobulin improves symptoms. A prospective, multi-center, randomized, controlled trial of 36 patients with IBS-D who completed an 8-week intervention showed the benefits of this therapy.

Medications

- Alpha-glucosidase inhibitors
- Saccharomyces boulardii
- Probiotics

Keywords

- IBS-D
- Nutritional therapy
- Serumborne immune globulin
- Protein isolate

For reference:

International Probiotics Association (2016). The LiveMood Gastrointestinal Microbiome Resource Center
Published Clinical Cases – Inflammatory Bowel Disease (IBD)

Management of inflammatory bowel disease with oral serum-derived bovine immunoglobulin

Case Series Investigating the Clinical Practice Experience of Serum-Derived Bovine Immunoglobulin/Protein Substitutes (IBI) in the Clinical Management of Patients with Inflammatory Bowel Disease

Use of a Nutritional Therapy, Serum-Derived Bovine Immunoglobulin/Protein Substitutes (IBI), to Achieve Improvement in Two Different Cases of Crohn’s Disease

Successful management of refractory ulcerative colitis with orally administered serum-derived bovine immunoglobulin therapy

Pilot Pharmacoeconomic Analysis of Serum-derived Bovine Immunoglobulin Use in IBD
https://www.youtube.com/watch?v=Zf4C-Plk908
Effect of SDP/SBI supplementation in Aging Model

Experimental design

INTESTINAL EFFECTS
Dietary supplementation with SDP will reduce the magnitude of intestinal dysfunction associated with aging

SYSTEMIC EFFECTS
Effects of SDP supplementation on inflammatory markers & plasma amino acid profile

CENTRAL NERVOUS SYSTEM EFFECTS
SDP supplementation may reduce the inflammatory state of the CNS during aging and prevents the cognitive dysfunctions
Intestinal Effect on Senescent Mice

Pro-inflammatory cytokines

Conclusions

Six month-old SAMP8 mice showed a low-grade inflammatory state in the jejunum mucosa. SDP supplementation was able to prevent this effect, confirming observations from other inflammatory models (SEB-In intestine, Colitis or LPS-Lung models).

⇒ Reduces the Inflammatory Effects in the Intestine
Systemic Effects on Senescent Mice

Six month-old SAMP8 mice showed a systemic low-grade inflammatory state. As previously observed in other inflammatory models (SEB-Intestine, Colitis or LPS-Lung models), SDP supplementation was able to prevent this effect.

⇒ Reduces Systemic Inflammation
Effects on the Central Nervous System

GUT BRAIN AXIS

Influence on:
- Weight Gain
- Bowel Movements
- Nutrient Delivery
- Microbial Balance

Influence on:
- Neurotransmitters
- Stress/Anxiety
- Mood
- Behaviour

SDP / SBI

MICROBIOTA
Effects on the Central Nervous System

Gut-Brain Axis

Nervous System / Blood

Microbiota

SDP/SBI

External environment

Hormones

Cytokines

Bacterial products

Neurons

GALT cells

Biological Functionality of Serum fractions, a Summary

Intestinal effects

- Immunosenesence
- Unspecific response

Systemic effects

- Pro-inflammatory cytokines
- Anti-inflammatory cytokines

CNS effects

- Cognitive improvement
- Blood Brain Barrier
- Pro-inflammatory cytokines
- Adhesion molecules
- Reactive Oxidative Species

Intestinal effects → Systemic effects → CNS effects

GUT-BRAIN AXIS

+ SDP/SBI
• APC and Entera Health’s Serum proteins are widely used in humans and other many species, including companion animals

• It is recognized that these functional proteins are a mixture of proteins that mitigate the negative effects of inflammation

• Used appropriately, functional proteins can be a tool to improve humans and animal well being