atlantia
CLINICAL TRIALS

# SUCCESS STORY

## How Atlantia Proved Chr Hansen's Bif195 Probiotic Strain Heals Asprin-Induced Ulcers In First-of-Its-Kind Trial

Atlantia Clinical Trials, in collaboration with Chr Hansen, APC Microbiome, and Mercy Hospital, lead the first trial to record a detailed time-course of aspirin-induced, small-intestinal damage and validate subsequent reversal of damage by Chr Hansen's specially selected probiotic strain, Bif195.

# How Atlantia Proved Chr Hansen's Bif195 Probiotic Strain Heals Asprin-Induced Ulcers In First-of-Its-Kind Trial

## Atlantia Clinical Trials leads first trial to record a detailed time-course of aspirin-induced, small-intestinal damage and show subsequent reversal of damage by bifidobacterium breve

**This unique trial aimed to assess how the Bif195 probiotic strain could diminish or reverse small intestinal mucosal damage and gastrointestinal (GI) symptoms caused by extended, low-dose Aspirin usage. The goal was to offer a safer option than current preventive measures for NSAID-related GI issues.**

> *This is the first trial to record a detailed time-course of aspirin-induced, small-intestinal damage. Even more impressive was the subsequent reversal of the damage by the bifidobacterium.*

Dr. Martin Buckley
Consultant gastroenterologist, Mercy University Hospital

## Chr Hansen's Needs

Chr Hansen needed a highly experienced research partner who could evaluate the deterioration of small intestinal mucosa tissue using a minimally invasive approach to avoid ethical concerns linked to more intrusive methods. Their key objectives were:

- Examine the Bif195 probiotic strain's efficacy in attenuating or reversing small intestinal damage resulting from prolonged, low-dose Aspirin usage.
- Employ capsule endoscopy as a non-invasive, reliable technique for evaluating intestinal damage.
- Ensure study design met ethical standards and delivered robust, reliable outcomes.

## Research Goals

**Primary Goal:** Assess Bif195's efficacy in reducing or reversing Aspirin-induced small intestinal mucosal damage via capsule endoscopy.

**Secondary Goals:**

- Evaluate Bif195's impact on GI symptoms and pain using the Gastrointestinal Symptom Rating Scale.
- Investigate changes in biomarkers of intestinal barrier function in blood and fecal samples due to the probiotic strain co-administered with Aspirin.

## Approach

### Study Design

Single-site, randomized, double-blind, placebo-controlled, two-armed, parallel-group trial.

ICH-GCP principles and applicable local regulatory requirements adhered to.

### Recruitment Criteria

- Healthy adult volunteers
- No history of chronic gastrointestinal diseases
- No recent use of probiotics or other GI-affecting medications
- Willing to comply with study protocol and provide informed consent

### Intervention & Monitoring

- **2-Week Run-in Period:** Participants maintained habitual lifestyle and diet, avoiding probiotics.
- **6-Week Intervention Period:** Participants received either the probiotic strain or placebo daily, alongside 300mg of Aspirin.
- **2-Week Post-Intervention Period:** Additional period of probiotic/placebo administration to evaluate intestinal healing post-Aspirin use.

## Data Collection

- **Capsule Endoscopy (CE):** Assessed small intestinal mucosal damage at 1 and 4 weeks.
- **GSRS Questionnaire:** Evaluated GI symptoms and pain throughout the study.
- **Biomarkers:** Collected blood and fecal samples at baseline, during, and after the intervention to analyze intestinal barrier function changes.

## Data Analysis

- **Primary Endpoint:** AUC for the Lewis Score from capsule endoscopy, measuring small intestinal damage over 8 weeks.
- **Secondary Endpoints:** AUC for ulcer number, pain syndrome score from GSRS, and biomarker changes.

Data compared the probiotic and placebo groups. With a sample size of 35 per group, allowing for a 15% drop-out rate, the goal was 30 participants per group. A 30% reduction in the AUC for the Lewis Score was deemed clinically significant.

## Results

The primary analysis showed that Bif195 significantly reduced the AUC for the Lewis Score, proving its efficacy in reducing Aspirin-induced intestinal damage. Secondary analyses revealed improvements in GI symptoms, pain scores, and biomarkers of intestinal barrier function.

## Conclusion

The trial showed Bif195 effectively reduces and reverses intestinal damage and GI symptoms from long-term low-dose aspirin use. Capsule endoscopy offered reliable, non-invasive assessment, positioning Bif195 as a safer alternative for NSAID-related GI injury prevention and paving the way for new treatments.

## Atlantia's Role

Atlantia's expertise was pivotal in this landmark study. We designed the trial to meet Chr Hansen's needs, using capsule endoscopy for non-invasive evaluation. We recruited healthy participants and monitored them rigorously, collecting data through GSRS questionnaires and biomarker analysis. Our meticulous execution provided robust evidence of the probiotic's efficacy and set a new standard for NSAID-induced GI damage research.

## Commercial Gains

### Forge Strategic Partnerships

The trial's success opened doors for co-developments, joint ventures, and expanded distribution, broadening Chr Hanen's market reach.

### Elevate Scientific Portfolio

Partnering with Atlantia, the trial featured on the cover of the high-impact journal Gastroenterology, boosting credibility, opening doors for further research.

### Drive Sales & Market Share

The trial's success with Atlantia gave Chr Hansen powerful, evidence-backed marketing material, boosting trust and differentiating their offering.

### Dominate the Market

By showcasing the ability to mitigate aspirin-induced gut damage, Chr Hansen solidified its position as a leader in gastrointestinal health.

### Drive Product Development

With no existing products clinically proven to protect against aspirin-induced gut damage, Chr Hansen began developing a new dietary supplement.