

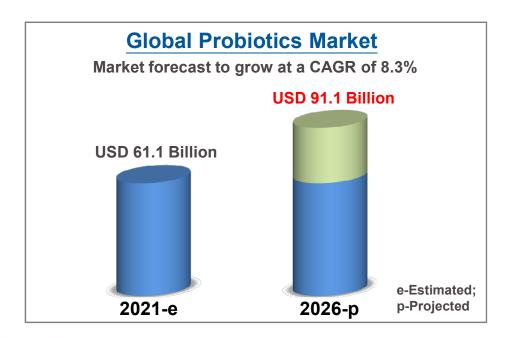
全球益生菌市場快速發展

Global probiotics market is growing rapidly

全球市場分析報告顯示,預計2026年全球益生菌市場約為911億美元。

The global market analysis report shows that the global probiotic market is expected to be

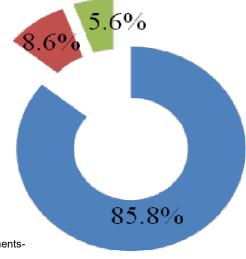
about 91.1 billion US dollars in 2026.



全球益生菌市場應用 Global probiotics market by product application

*市場分布 MARKET SHARE

- 一功能性食品Functional food
- 一保健食品與藥品Health food and medicine
- ── 益生菌原料Probiotics raw material





https://www.reportlinker.com/p05129364/Probiotics-Market-by-Application-Dietary-Supplements-Animal-Feed-Source-Form-End-User-And-Region-Forecast-to.html?utm_source=GNW; https://www.researchandmarkets.com/reports/5370159/global-probiotics-market-by-application

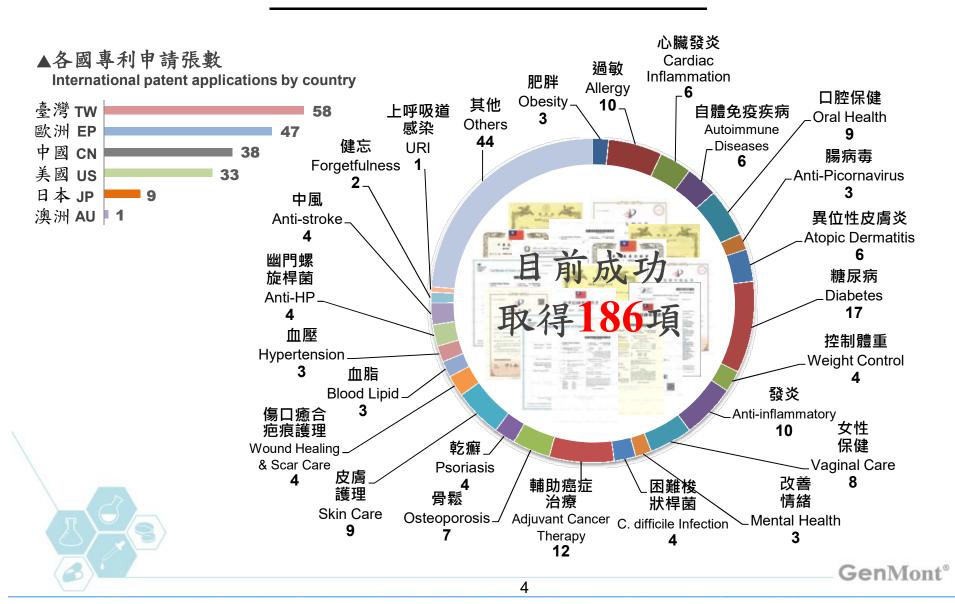


2024年度研究成果介紹 The Annual Research Presentation 2024



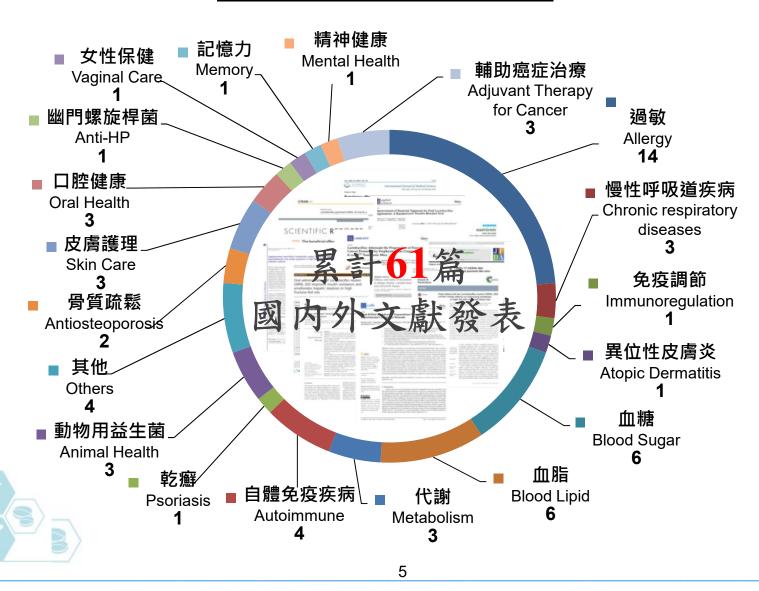
186項研發專利

Patents over the world



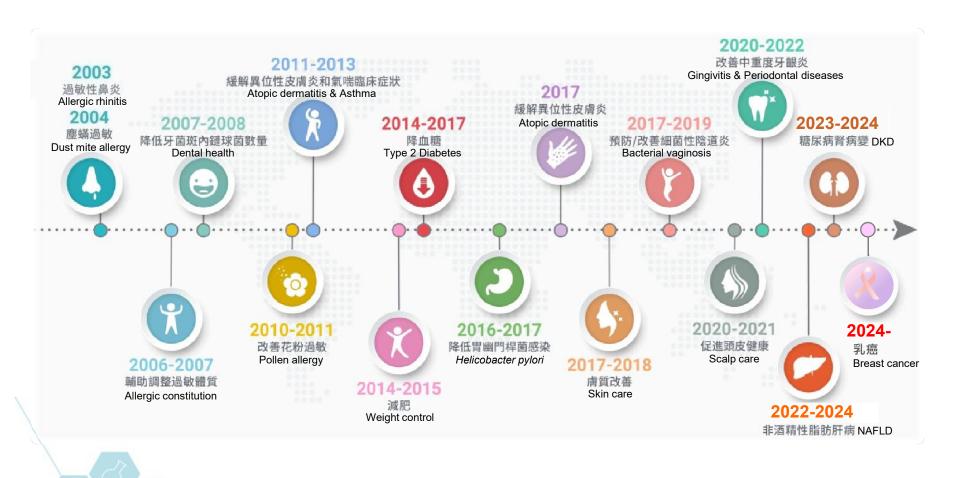
61篇文獻發表

Published Papers



人體臨床試驗列表

Human clinical trials



評估益生菌對於非酒精性脂 防肝病患者的效益以及腸道 微生物所扮演的調節角色

摘要:

以早期非酒精性脂肪肝病患者食用6個月複合益生菌粉 (熱滅活羅伊氏乳桿菌 GMNL-263+羅伊氏乳桿菌 GMNL-74)的臨床試驗結果,分析慢性發炎情形、全身性氧化壓力、碳水化合物和脂肪代謝,以及腸道微生態等指標,來評估益生菌對於非酒精性脂肪肝病的改善作用和預防惡化的機制。

試驗開始時間: 2022年7月14日

完成時間: 2024年3月

完成人數:60人

試驗型態:隨機分派的對照雙盲試驗

入案條件:

- -20~80歲成年人/老人
- -超音波診斷為非酒精性脂肪肝
- -丙胺酸轉胺酶 (ALT, 肝功能指數) 檢測值為60-300 U/L





Brief Summary

In this study, the improvement of the clinical status of early-stage non-alcoholic fatty liver disease (NAFLD) patients after the probiotic intervention will be assessed. And the mechanism of probiotics to prevent the progression of illness would be investigated. The chronic inflammation status, systemic oxidative stress, metabolism of carbohydrates and lipid, and gut microbiota of NAFLD patients will also be analyzed.

Study Start (Actual): 2022-07-14

Study Completion: 2024-03 **Enrollment (Completed)**: 60

Study Type:

Interventional (Randomized Controlled Trail)
Masking: Double (Participant, Investigator)

Dietary Supplement:

Probiotic group (Lactobacillus reuteri GMNL-263 (heat-killed) and GMNL-89 (alive) and Lactobacillus rhamnosus GMNL-74 (alive))

Other: Placebo group

Eligibility Criteria

- -Ages Eligible for Study: 20 Years to 80 Years (Adult, Older Adult)
- -Inclusion Criteria:
- •Diagnosis of Nonalcoholic fatty liver disease (NALFD) by ultrasound.
- •The range of Alanine aminotransferase (ALT) blood test is 60-300 U/L

評估益生菌對於糖尿病腎病 變患者的效益以及腸道微生 物發揮的調節作用

摘要:

進行為期6個月的臨床試驗,讓糖尿病腎病變患者食用複合益生菌粉(羅伊氏乳桿菌 ADR-1+鼠李糖乳桿菌 GM-020),並監測血糖和腎功能相關指標。預期實驗結果,複合益生菌粉將經由抑制有害菌來改變腸道微生的粉與脂肪的代謝來改善糖尿病腎病變的無化。

試驗開始時間: 2023年4月24日

完成時間: 2024年8月

完成人數: 44人

試驗型態:隨機分派的對照雙盲試驗

入案條件:

- -25~80歲成年人/老人
- -患有第2型糖尿病並穩定服藥3個月
- -餐前 HbA1c 檢測在 7~10%
- -第1-3a 期糖尿病腎病變 (eGFR > 45 mL/min)
- -微量白蛋白尿達到 30~300 mg/day



Brief Summary

To evaluate the efficacy of probiotics in the treatment of diabetic kidney disease, this study is designed to explore after consumption of probiotics lactobacillus reuteri ADR-1 and lactobacillus rhamnosus GM-020 composite strain powder sachets for 6 months, whether the improvement of blood sugar, kidney related indicators can further improve the course of diabetic kidney disease. The clinical trial predicted that probiotics can improve diabetic kidney disease by changing the intestinal flora by inhibiting harmful bacteria, reduction of systemic oxidative stress, balance carbohydrate and fat metabolism, further preventing the progress of diabetic kidney disease.

Study Start (Actual): 2023-04-24 Study Completion: 2024-08 Enrollment (Completed): 44

Study Type:

Interventional (Parallel Assignment, Randomized Controlled Trial)

Masking: Double (Participant, Investigator)

Eligibility Criteria

- -Ages Eligible for Study: 25 Years to 80 Years (Adult, Older Adult)
- -Inclusion Criteria:
- •Suffering from type 2 diabetes and stable medication for 3 months
- •Detection of HbA1c before meals between 7% and 10%
- •Stage 1-3a diabetic nephropathies (eGFR > 45 mL/min)
- •Microalbuminuria estimated between 30 to 300 mg/day

評估益生菌在乳癌患者的 臨床效益

摘要:

化療相關的副作用會影響治療效 果、生活質量,且對乳癌基者 成永久性傷害。因此透過本研究 成來探討在乳癌化療時,服用複合 益生菌粉包6個月後,是否能減 輕化療副作用,進而幫助患者順 利完成療程。

試驗開始時間: 2024年4月8日

預計完成時間: 2026年4月1日

預計收案人數:70人

試驗型態:隨機分派的對照雙盲試驗

入案條件:

- -20~80歲成年人/老人
- -有接受anthracycline和taxane化學治療的1~3期 乳癌患者(不限於化學治療/手術前後)
- -BMI $> 18 \text{ kg/m}^2$
- -經醫師評估且自願參加者



ClinicalTrials.gov

RECRUITING (1)

To Evaluate the Clinical Efficacy of Probiotics in Patients With the Breast Cancer

ClinicalTrials.gov ID 1 NCT06039644

Sponsor 1 GenMont Biotech Incorporation

Last Update Posted 1 2024-04-12

Brief Summary

Chemotherapy-associated side-effects would affect therapeutic effect, quality of life, and cause permanent harm to breast cancer patients. This study is designed to explore after consumption of probiotics of lactobacillus composite strain powder sachets for 6 months in breast cancer chemotherapy, and whether the improvement of meliorate the side effects, further assists patients completing the chemotherapy.

Study Start (Actual) : 2024-04-08

Study Completion (Estimated): 2026-04-01

Enrollment (Estimated): 70

Study Type:

Interventional (Parallel Assignment, Randomized Controlled Trial)

Masking: Double (Participant, Investigator)

Eligibility Criteria

- -Ages Eligible for Study: 20 Years to 80 Years (Adult, Older Adult)
- -Inclusion Criteria:
- •Stage I-III breast patients using anthracycline-based and taxane-based chemotherapy (not limited before or after chemotherapy/surgery)
- •BMI $> 18 \text{ kg/m}^2$
- •Patients judged by physicians to participate in this trial and who are willing



乳酸桿菌功效研究

Efficacy studies of Lactobacillus

題目:奈米粒強化之後生元:以有效的載體運輸方式革新傳統癌症治療

Article: Nanoparticle-enhanced postbiotics: Revolutionizing cancer therapy through effective delivery. Life Sci. 2023 Dec 23:122379.

摘要:胃癌是導致癌症死亡的重大原因。其常用的化學治療方式因伴隨著嚴重的副作用而面臨挑戰,因而促使其他治療方式的開發研究,像是本篇所使用的後生元(從滅活益生菌衍生而來且更具安全性的生物分子)。儘管從體外試驗結果看來,後生元運用在癌症治療上是很有願景的,但在體內傳輸系統中是否能有效發揮作用仍是個挑戰。有鑑於此,本研究目標以奈米微粒結構來包埋 Lacticaseibacillus paracasei GMNL-133 (SGMNL-133),探討奈米後生元在加強胃癌治療上的效果。透過優化GMNL-133 裂解液的萃取和管柱沖提方法後,得到SGMNL-133,並開發奈米微粒來保護SGMNL-133免受胃酸影響,且能利用奈米微粒結構來加強黏膜穿透性,使更有效地將所裝載的功能性分子送到病灶處,提高跟胃癌細胞的相互作用,順利發揮抗癌治療效果。

Abstract: Gastric cancer contributes to cancer-related fatalities. Conventional chemotherapy faces challenges due to severe adverse effects, prompting recent research to focus on postbiotics, which are safer biomolecules derived from nonviable probiotics. Despite promising in vitro results, efficient in vivo delivery systems remain a challenge. This study aimed to design a potential nanoparticle (NP) formulation encapsulating the *Lacticaseibacillus paracasei* GMNL-133 (SGMNL-133) isolate to enhance its therapeutic efficacy in treating gastric cancer. Our study optimized the extraction of the lysate and column elution of GMNL-133, yielding SGMNL-133. We also developed NPs to protect SGMNL-133 from gastric acid, enhance mucus penetration, and improve the interaction with gastric cancer cells. This combination significantly enhanced drug delivery and anti-gastric tumor activity.



乳酸桿菌功效研究

Efficacy studies of Lactobacillus

題目:乳酸桿菌透過增加蕈狀體神經細胞中的乳酸脫氫 酶含量來改善果蠅記憶力

Article: Probiotic Lactobacillus spp. improves Drosophila memory by increasing lactate dehydrogenase levels in the brain mushroom body neurons.

Gut Microbes. 2024 Jan- Dec;16(1):2316533.

摘要:益生菌是活的微生物,具有為宿主帶來健康效益的潛力,有時候還能 影響行為反應。然而,益生菌影響宿主行為的詳細機制和潛在的生物效應仍 不清楚。有鑒於此,透過在轉譯研究過程中,使用一種成熟的模式生物-黑腹 果蠅和廣為人知的乳酸桿菌屬益生菌,來探討宿主與腸道微生物群之間的相 互作用。實驗結果顯示,給予5天的GMNL-185和GMNL-680益生菌組合物在 有顯著改善記憶功能的效果。其食用益生菌組合物的改善程度,藉由氣味訓 練後的活體果蠅大腦蕈狀體神經細胞的鈣離子影像變化,可看到蕈狀體的β 和y蕈杯 (lobes) 的鈣離子影像反應增加。另外,在定量反轉錄聚合酶連鎖反 應分析和全腦免疫組織化學染色結果看到,乳酸脫氫酶 (LDH) 表現量顯著增 加。綜合上述結果證實,GMNL-185和GMNL-680益生菌組合物是經由增加 腦中乳酸脫氫酶含量來加強果蠅的記憶功能。

Abstract: Probiotics are live microorganisms that offer potential benefits to their hosts and can occasionally influence behavioral responses. However, the detailed mechanisms by which probiotics affect the behavior of their hosts and the underlying biogenic effects remain unclear. Lactic acid bacteria, specifically Lactobacillus spp. are known probiotics. Drosophila melanogaster, commonly known as the fruit fly, is a well-established model organism for investigating the interaction between the host and gut microbiota in translational research. Herein, we showed that 5-day administration of a combined diet of L. acidophilus GMNL-185 and L. rhamnosus GMNL-680 demonstrated synergistic effects on memory functions. Live brain imaging revealed a significant increase in calcium responses to the training odor in the mushroom body β and γ lobes of flies that underwent mixed feeding with GMNL-185 and GMNL-680. Quantitative reverse transcription polymerase chain reaction (qRT-PCR) and whole-mount brain immunohistochemistry revealed significant upregulation of lactate dehydrogenase (LDH) expression in the fly brain following the mixed feeding. Altogether, our results demonstrate that supplementation with L. acidophilus and L. rhamnosus enhances memory functions in flies by increasing brain LDH levels.



roduce and utilize various neurotransmitters, acluding norepinephrine, dopamine, serotonin, and gamma-aminobutyric acid (GABA),6 which opment of various diseases,10 affect the physiological responses of the hosts.'

Accumulated evidence suggests that the gut microgut microbiota on host health predominantly siome is intricately involved in virtually all aspects employed mammalian models. Numerous studie

the precise interactions between the gut microbiot human health, and altering the composition of the gut microbiota could potentially impact the physiological responses of the box, leading to clicial microorganisms, such as bacteria or years. neural and behavioral changes. ¹⁻³ Gut microbiome that naturally inhabit the human body. Probiotic commune system of the host. ⁴⁻⁵ Gut microbes can did that been reported that probiotics could alle-

CONTACT Chie-Lin Wu Chundhall gundulm Department of Biochemistry, Department of Riccolland Sciences, Department of Biocedical Sciences, College of Marketon, Charac Gara University, Tax

乳酸桿菌功效研究

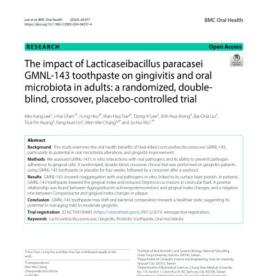
Efficacy studies of Lactobacillus

題目:經隨機雙盲、交叉設計具安慰劑對照組之試驗, 探討副乾酪乳桿菌GMNL-143牙膏對於成人牙齦炎和 口腔菌相的影響

Article: The impact of Lacticaseibacillus paracasei GMNL-143 toothpaste on gingivitis and oral microbiota in adults: a randomized, doubleblind, crossover, placebo-controlled trial. BMC Oral Health. 2024 Apr 20; 24 (1):477.

摘要:本研究在探討熱滅活副乾酪乳桿菌GMNL-143對於口腔健康的益處,尤其在調節口腔菌相和改善牙齦炎的潛力上。透過隨機雙盲、交叉設計的臨床試驗,先使用4周的試驗牙膏 (GMNL-143或安慰劑)後,進入1周的廓清期停止使用試驗牙膏,接著再交換使用4周的試驗牙膏,來評估GMNL-143牙膏對於牙齦炎症狀的改善程度。臨床試驗結果顯示,使用GMNL-143牙膏可降低牙齦炎指數,和減少牙齦溝液中的變異鏈球菌 (S. mutans) 含量。且從牙菌斑菌相中觀察到,牙齦指數與牙周致病菌含量呈正相關,而與彎麴菌屬呈負相關。綜合上述結果,GMNL-143牙膏可讓口腔菌相組成往較健康的口腔微生態發展,更證明了GMNL-143的確具有改善輕度到中度牙齦炎的潛力。

Abstract: This study examines the oral health benefits of heat-killed *Lacticaseibacillus paracasei* GMNL-143, particularly its potential in oral microbiota alterations and gingivitis improvement. A randomized, double-blind, crossover clinical trial was performed on gingivitis patients using GMNL-143 toothpaste or placebo for four weeks, followed by a crossover after a washout. The results show that GMNL-143 toothpaste lowered the gingival index and reduced *Streptococcus mutans* in crevicular fluid. A positive relationship was found between *Aggregatibacter actinomycetemcomitans* and gingival index changes, and a negative one between *Campylobacter* and gingival index changes in plaque. In summary, GMNL-143 toothpaste may shift oral bacterial composition towards a healthier state, suggesting its potential in managing mild to moderate gingivitis.



■ BMC

財務狀況 Financial status

※母公司財報-景岳生技 Separate Financial Statements-GenMont

單位:千元 In Thousands of New Taiwan Dollars	110母公司財報 (Year 2021 Single)	111年母公司財報 (Year 2022 Single)	112年母公司財報 (Year 2023 Single)
營業收入NET REVENUE	427,929	368,546	309,445
營業毛利GROSS PROFIT	299,326	258,019	211,231
營業費用OPERATING EXPENSES	(150,140)	(131,953)	(135,011)
營業利益INCOME(LOSS) FROM OPERATIONS	149,186	126,066	76,220
營業外損益NON- OPERATING INCOME AND EXPENSES	(6,231)	(50,291)	(37,497)
稅前淨利INCOME(LOSS) BEFORE INCOME TAX	142,955	75,775	38,723
税後淨利NET INCOME(LOSS)	113,132	56,978	32,991

財務狀況 Financial status

※合併財報 Consolidated Financial Statements

單位:千元	111年合併	112年合併	113前二季合併
In Thousands of New Taiwan	(Year 2022	(Year 2023	(Year 2024 H1
Dollars	Consolidated)	Consolidated)	Consolidated)
營業收入NET REVENUE	368,546	318,015	210,603
營業毛利GROSS PROFIT	256,717	211,192	139,291
營業費用OPERATING EXPENSES	(194,747)	(204,204)	(98,903)
營業利益INCOME(LOSS) FROM OPERATIONS	61,970	6,988	40,388
營業外損益NON-OPERATING INCOME AND EXPENSES	4,288	21,175	17,736
稅前淨利INCOME(LOSS) BEFORE INCOME TAX	66,258	28,163	58,124
稅後淨利NET INCOME(LOSS)	47,461	22,431	44,890
停業單位損益Income (Loss)from Discountinued Operations	0	0	0
本期淨利NET INCOME(LOSS)	47,461	22,431	44,890

風險評估 Risk Assessment

生技領域方面財務風險Financial risk in the biotech sector

- 研發期間長 Long R & D period
- 獲利回收晚 Late profit recovery
- ➡ 可能因此導致資金不足 Which may lead to insufficient funds

益生菌市場持續成長Probiotics market continues to grow

根據Precedence Research預估,2021年至2030年全球益生菌市場年平均複合成長率(CAGR)將可達8.7%,至2030年時其規模可達1,339億美元;其中食品飲料市場的規模最大(達75%以上),動物飼料則成長最快速。目前市場以亞太地區為主,市場占比超過七成。

According to Precedence Research estimates, the global probiotics market will reach an average annual compound growth rate (CAGR) of 8.7% from 2021 to 2030, and its scale will reach US\$133.9 billion by 2030; the food and beverage market is the largest (up to 75% or more), animal feed is the fastest growing. At present, the market is dominated by the Asia-Pacific region, accounting for more than 70% of the market.



Thanks For Your Attention

