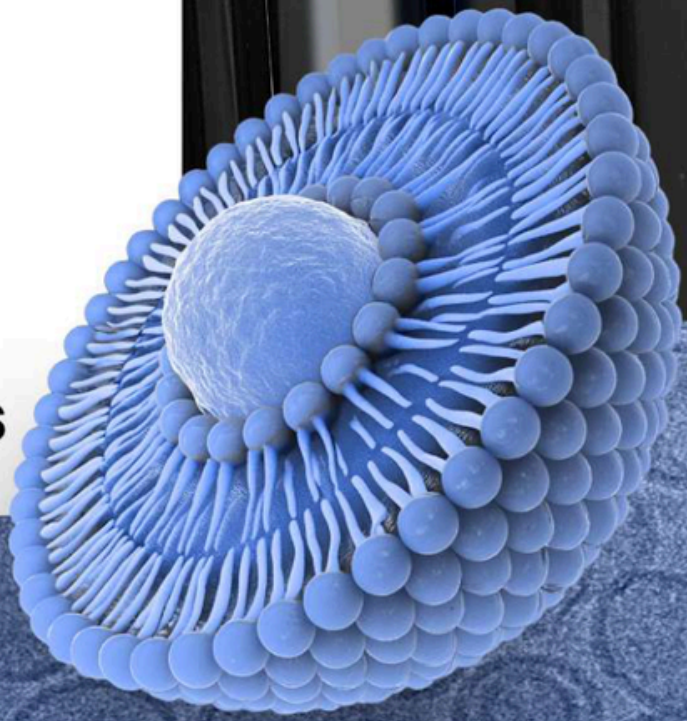
Brain market

Human Clinical Study on the Comparative Bioavailability of Various Iron Supplementation Forms



Summary of the Study[1]

Abstract

The purpose of this study was to compare the bioavailability of Iron in liquid liposomal supplementation form provided by BrainMax liquid liposomal iron with other non-liposomal forms provided by competitors. Thirty metabolically healthy volunteers were enrolled in the study.

Overall, BrainMax liquid liposomal iron **had the highest bioavailability, up to 397.7 times more,** compared Iron supplementation forms tested.

KEYWORDS: Iron, Mineral, Liposomes, Bioavailability, Dietary Supplements, Biohacking.

Product Groups

LLI
Liquid Liposomal Iron 15 mg

Manufactured for BrainMarket

PI
Non-liposomal powder Iron 15 mg

Manufactured by Competitor in Germany

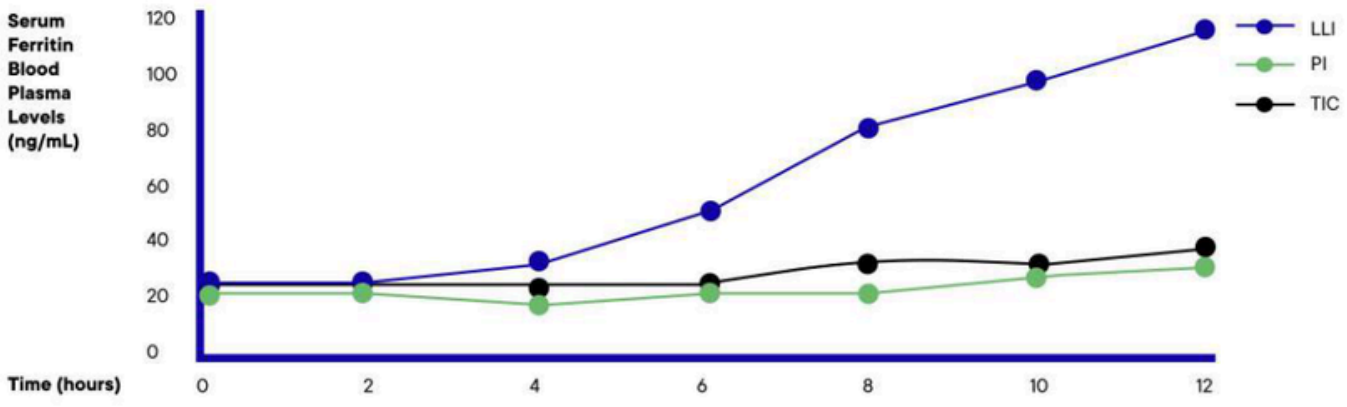
TIC
Non-liposomal tablet Iron + vitamin C 40 mg + 40 mg

Manufactured by Competitor in Germany

Results

During the study, Iron (ferritin) blood plasma levels were measured over time after the intake of Iron in three supplementation forms, namely LLI, PI, and TIC.

The results have shown that the BrainMax Liquid Liposomal Iron (LLI) has **397.7 times** higher bioavailability than the competitor's non-liposomal powder Iron (PI), and **44.4 times** higher bioavailability than the competitor's non-liposomal tablet Iron (TIC). Liposomal Iron also **maintained elevated plasma levels throughout the entire study period**, proving sustained highest concentrations during daily supplementation.



[1]See the full study from page 2.

Introduction

Iron is a vital mineral with numerous functions in the human body. It supports normal cognitive function, energy-yielding metabolism, and the formation of red blood cells and hemoglobin. Additionally, Iron is essential for a well-functioning immune system, helps reduce tiredness and fatigue, and plays a key role in the process of cell division.[1]
Despite its critical role, Iron exhibits low bioavailability, which significantly restricts its effectiveness.[2] Some studies recommend the use of absorption enhancers, such as vitamin C, to improve Iron uptake.[3] **Liposomal encapsulation have emerged as a highly effective solution for improving Iron supplementation.**[4] The current study confirms that **unique advanced liposomal technology, LipoSone™ used by BrainMax**, maximizes Iron bioavailability, outperforming conventional supplementation forms.

Method

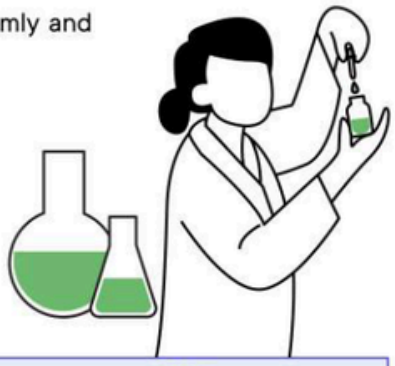
The current study was a randomized, controlled, three-group trial investigating the effect of Iron in three different formulations: 15 mg liquid liposomal Iron provided by BrainMax (LLI), 15 mg non-liposomal Iron powder provided by competitor (PI), and 40 mg non-liposomal Iron with added vitamin C in tablet form provided by competitor (TIC).

Participants

Thirty (30) metabolically healthy volunteers were enrolled in the study. They were randomly and evenly assigned to one of the three supplementation groups.

Exclusion criteria for participants were:

- ✖ <20 and >50 years of age
- ✖ Any diagnosis of chronic condition(s)
- ✖ BMI outside of the normal category range (18.5–24.9kg/m2)
- ✖ Presence of acute illness
- ✖ Use of drugs or dietary supplements on a frequent and/ or mandatory basis



Measurements	LLI*	PI*	TIC*
Age (years)	29 ± 6	29 ± 5	29 ± 4
Females (%)	50	40	60
BMI (kg/m2)	20 ± 2	21 ± 2	21 ± 1
Systolic BP (mmHg)	120 ± 9	121 ± 12	119 ± 7
Diastolic BP (mmHg)	78 ± 6	80 ± 7	79 ± 5

Table 1. Participant Anthropometric Data

** Mean standard deviation n=10*

Active Substances & Supplementation Groups

a. Liquid liposomal Iron saccharate (LLI): BrainMax Liquid Liposomal Iron

b. Non-liposomal powder Iron (PI): Competitor's Iron 15 mg from 44.11 mg Iron saccharate powder dissolved in 100 mL water, manufactured in Germany.

c. Non-liposomal tablet Iron Bisglycinate (TIC): Competitor's Iron 40 mg with added vitamin C 40 mg in tablet form, manufactured in Germany.

Dosage and Blood Collection

Participants in the designated supplement groups, while in a fasted state, received an oral dose of the respective supplements. Blood samples were taken initially before the supplement was consumed (baseline) and then at intervals of 2, 4, 6, 8, 10 and 12 hours following the intake. These samples were microcentrifuged for 12 minutes, cooled to 4°C, and analysed for plasma ferritin levels using Roche Tina-quant Diagnostics Hitachi 912 system.

Data

All participants successfully completed the study. They were predominately in their late twenties, with an equal distribution of males and females. All were characterized by healthy Body Mass Index (BMI) and blood pressure levels, detailed by both systolic and diastolic measurements. Participant anthropometric data is provided in **Table 1.**

Each group's average blood plasma ferritin levels over time are graphically represented in **Figure 1**. Pharmacokinetic parameters, such as the peak plasma concentration of Iron (C_{max}) and the time to reach this peak (T_{max}), are documented in **Table 2**.

The area under the concentration-time curve (AUC_{0-t}) was calculated from dosing to the last measurable concentration using the trapezoidal rule, indicating the total exposure to the active ingredient over time. The incremental area under the curve (iAUC) adjusts the AUC for baseline variations. The Oral Bioavailability Value (OBV) was determined by comparing the liposomal and non-liposomal $iAUC_{0-t}$ values.

Results

The data for the non-liposomal groups closely overlaps with the baseline, showing that serum ferritin levels after supplementation with non-encapsulated Iron remain unchanged compared to pre-supplementation levels. To validate this observation, statistical analysis was conducted using Tukey's Honest Significant Difference (HSD) test, a post-ANOVA procedure for identifying significant differences between groups. This analysis compared the non-liposomal groups to each other and to the baseline, assessing the effects of PI and TIC supplementation on serum ferritin levels.

HSD Test Results:

No significant differences were observed between the baselines of the three supplementation groups — liposomal, and the two non-liposomal groups — **within the first 4 hours**.

No significant differences were found between non-liposomal groups and baseline values. This indicates that serum ferritin levels remained unchanged, regardless of the intake of non-liposomal products at dosages of either 15 mg or 40 mg of elemental Iron.

The liposomal group exhibited significantly higher serum ferritin levels **after 8 hours** compared to both non-liposomal groups.

A temporal analysis of ferritin plasma levels reveals that:

At baseline, the plasma ferritin levels across the three supplementation groups were comparable.

After 6 hours, the LLI group demonstrated significantly higher serum ferritin levels compared to the non-liposomal groups.

After 10 hours, the LLI group continued to show an **almost linear increase** in serum ferritin levels, while the PI and TIC groups showed no significant deviation from baseline.

After 12 hours, the LLI group reached the highest serum ferritin levels recorded in the study.

Considering the **iAUC** values, the outcomes suggest:

The liposomal group has an OBV **397.7 times** greater than the powder group, and **44.4 times** greater than the tablet group.

Measurements	LLI	PI	TIC
C_{max} (ng/mL)	111.4	27.3	34.4
T_{max} (hours)	12	2	12
AUC_{0-t} (ng*h/mL)	675.5	289.4	330.3
$iAUC_{0-t}$ (ng*h/mL)	397.7	1.0	44.4
OBV	-	397.7	44.4

Table 2. Pharmacokinetic Parameters Data

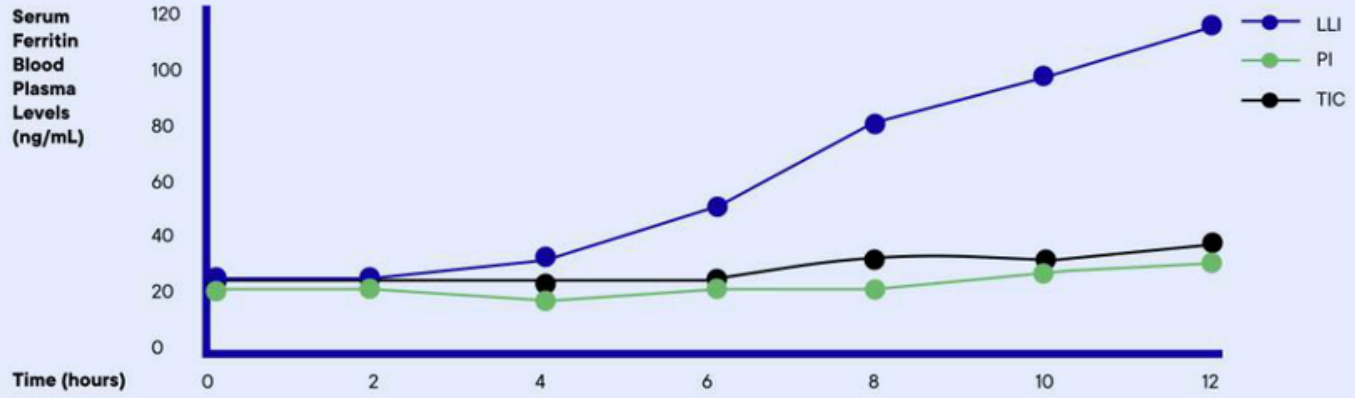


Figure 1. Serum ferritin blood plasma levels collected over time in three supplementation groups, namely LLI BrainMax Liquid Liposomal Iron, PI Iron saccharate powder form manufactured by competitor, and TIC Iron bisglycinate tablet form manufactured by competitor.

Discussion and Conclusion

The present study demonstrates that [redacted] exhibits **the highest bioavailability** among the tested groups. Specifically, LLI has **397.7 times** higher bioavailability than the competitor's non-liposomal powder form (PI), and **44.4 times** higher bioavailability than the competitor's Iron with added vitamin C in tablet form (TIC).

After six hours, ferritin plasma levels of the liposomal group were significantly higher than that of the non-liposomal groups. In contrast, the PI and TIC groups did not show any significant variation from the baselines. Additionally, LLI group **maintained elevated ferritin plasma levels** throughout the **entire 12-hour** duration of the study. On the other hand, no significant differences were found between PI and TIC groups and baseline values. This indicates that serum ferritin levels remained unchanged, regardless of the intake of non-liposomal products at dosages of either 15 mg or 40 mg of elemental Iron.

These findings underscore the substantial impact of liquid liposomes on Iron bioavailability and highlight the superior performance of PlantaCorp's liposomal formulations.

Overall, unique advanced liposomal technology, LipoSone™ used by BrainMax, is the most effective way to deliver Iron to the bloodstream while maintaining the highest blood plasma levels for up to 12 hours.

1. Commission E. EU Register of nutrition and health claims made on food. 2013. https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register.
2. Rout SR, Pradhan D, Haldar J, Rajwar TK, Dash P, Dash C, Rai VK, Kar B, Ghosh G, Rath G. Recent advances in the formulation strategy to improve iron bioavailability: A review. Journal of Drug Delivery Science and Technology, 2024, 95 (105633). doi: 10.1016/j.jddst.2024.105633.
3. Basrowi RW, Dilantika C. Optimizing iron adequacy and absorption to prevent iron deficiency anemia: The role of combination of fortified iron and vitamin C. World Nutrition Journal, 2021, 5 (1-1): 33-39. doi: 10.25220/WNJ.V05.S1.0005.
4. Maladkar M, Sankar S, Yadav A. A Novel Approach for Iron Deficiency Anemia with Liposomal Iron: Concept to Clinic. Journal of Biosciences and Medicines, 2020, 8: 27-41. doi: 10.4236/jbm.2020.89003.

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