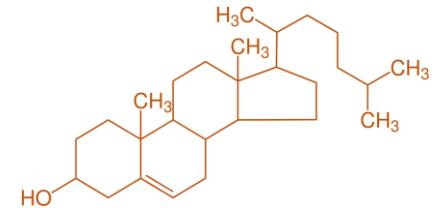
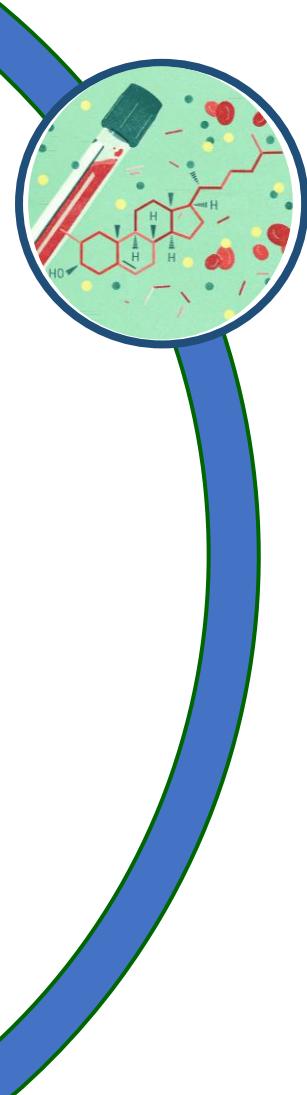


Effect of the consumption of Aquilea® Cholesterol on subjects with mild hypercholesterolemia: A nutraceutical intervention study in community pharmacies in the province of Tarragona.

FARMAGONACOL



OBJETIVES

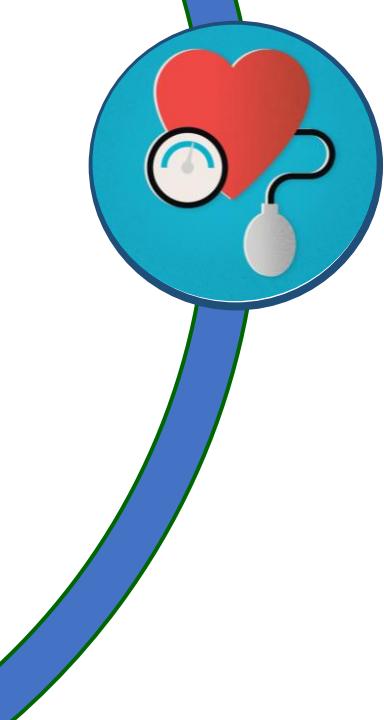


To assess plasma cholesterol concentrations after 1 and 2 months of nutraceutical intervention.

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Study the effects on other CV risk factors (BMI, BP and IFCC-Hbc1A).

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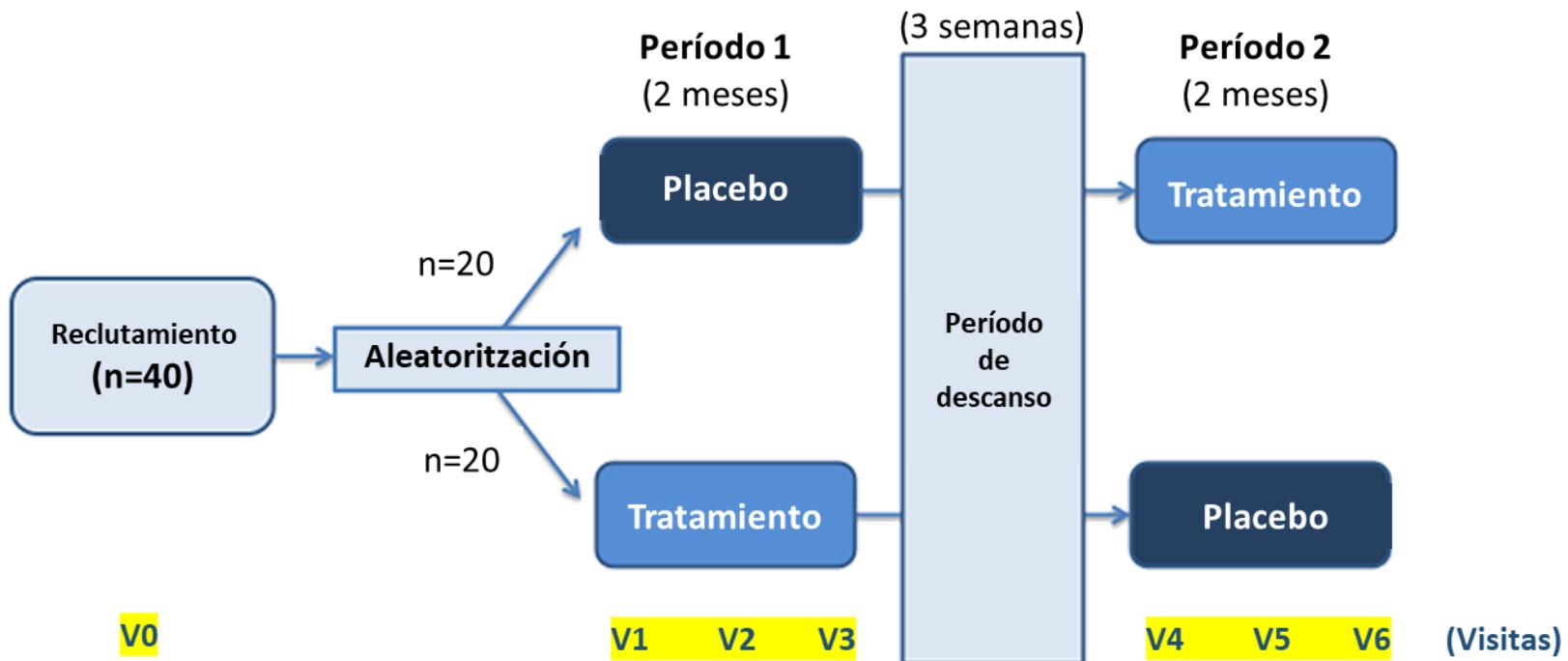


Promote the figure of pharmacists as health personnel qualified to participate in clinical trials.

Desing

- Men and Women between 35-69 years.
- Total Cholesterol = 200-250 mg/dL
- cLDL = 115-160 mg/dL.

Randomized Cross-over Triple-blind Placebo Controlled



Variables BIOQUÍMICAS (capilar blood)

- Fasting determination of Total Cholesterol, cLDL, cHDL, TGs y IFCC-HbA1c.



1

Power on the instrument and touch
Patient Test.



2

Open the lid, lance the finger and place the
drop of blood on the test disc.



3

Place test disc in the **cobas b 101** and close
lid. The measurement starts automatically.

Variables ANTROPOMÉTRICAS

- Peso corporal
- Perímetro de la cintura
- Presión arterial sistólica (PAS) y diastólica (PAD)



Registro de hábitos saludables

- Dieta últimas 48h
- Actividad física 48h



Nutracéutico

- 2,95 mg de monacolina K
- 2,27 mg tansinona IIA
- 10 mg policosanol
- 50 mg extracto de coriandro
- 800 mg de fitoesteroles
- 22 mg de oleorupeína
- 12 mg de vitamina E.



DIETA Y HÁBITOS SALUDABLES ESTUDIO FARMAGONACOL

CONSUME DIARIAMENTE

- Cinco raciones de **frutas y verduras**
2-3 piezas de fruta y 2 platos con verduras (crudas, cocidas, puré...)
- Fuentes variadas de **hidratos de carbono** complejos
Pasta integral, pan integral, patatas, arroz integral, avena, legumbres...
- Tres raciones de alimentos ricos en **proteínas**
Pescado, legumbres, huevos, carne, tofu...
- Alguna fuente de **probióticos**
Yogur natural, kefir, legumbres, productos fermentados...
- Alimentos ricos en **calcio y vitamina D**
Lácteos y derivados, bebidas vegetales enriquecidas, pescado azul...
- Alimentos ricos en **omega-3**
Pescado azul, frutos secos, semillas...

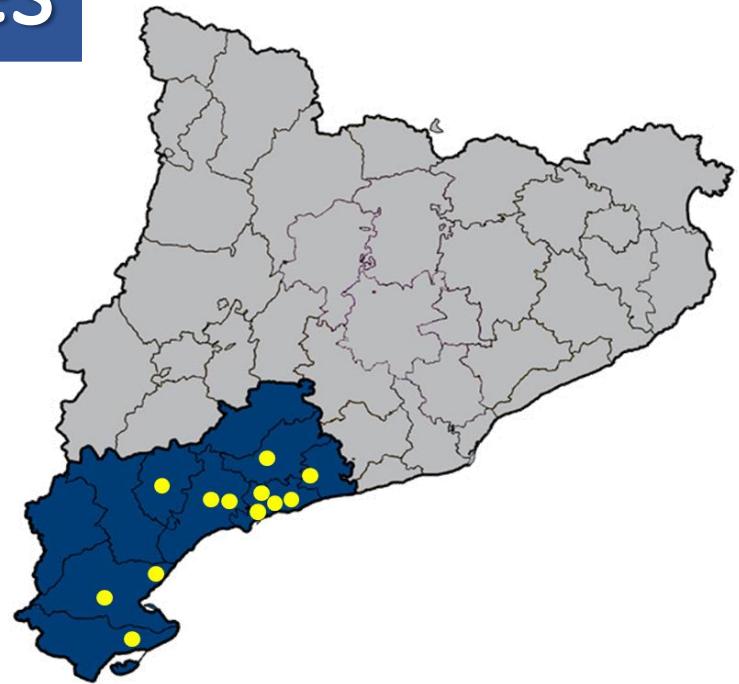
Y RECUERDA...

- ✓ Consume **alimentos de temporada y proximidad**.
- ✓ Prioriza el **aceite de oliva virgen extra** para cocinar y aliñar.
- ✓ Bebe de uno a dos litros de **agua al día**.
- ✗ Reduce el consumo de **alimentos precocinados** y de **alcohol**.
- ✗ Reduce el **azúcar añadido** (en el café, en el yogur...) e intenta utilizar otras formas para endulzar (fruta, canela...).
- ✗ Reduce el consumo de **carne**.
Consuma carne roja una vez a la semana, carne blanca dos o tres veces a la semana, y sustitúyela por otras fuentes de proteína como pescado, huevo, legumbres, tofu...
- ✓ Realiza **ejercicio físico** regularmente.
Intenta llegar a los 10.000 pasos diarios (ir caminando al trabajo, subir y bajar escaleras, aparcar un poco más lejos, bajar del bus una parada antes...)
- ✓ **Duerme** entre siete y nueve horas diarias.
- ✗ Reduce el uso de **pantallas** por la noche.



Farmacias participantes

- ALBIOL (Deltebre)
- AYTES (L'Ametlla de Mar)
- CEPERO (Riudoms)
- CLIMENT (Valls)
- COGUL (Torredembarra)
- CORTIELLA (Falset)
- FELIPE (Tarragona)
- FERNÁNDEZ (Tarragona)
- GAS (El Vendrell)
- PAYO (Tarragona)
- RODRÍGUEZ (Reus)
- SAURAS (Tortosa)



CRITERIOS DE INCLUSIÓN

- Disponer de un espacio reservado.
- Disponer de los equipos analíticos
- Disponer de contenedores de plástico para el deshecho de material biológico.

Análisis estadístico

- Las diferencias en las características basales entre secuencias de administración se han evaluado mediante pruebas ANOVA y X^2 .
- Las diferencias intra e inter-tratamiento se han evaluado mediante una prueba ANCOVA ajustada por edad, sexo y secuencia de administración de los tratamientos.
- Las diferencias intra-tratamiento se han evaluado también mediante un **Modelo lineal general** para evaluar la tendencia de los valores a lo largo de las intervenciones.

Resultados

Diagrama de flujo de los participantes



Reclutamiento <3 meses

Abandonos totales <7%

Results

BASELINE PARAMETERS

- A higher percentage of women are observed in Treatment B compared to Treatment A.
- Higher systolic blood pressure values in Treatment A compared to those in Treatment B.
- No differences were observed in the rest of the variables evaluated.

	Sequence 1 (n = 21)	Sequence 2 (n=22)	P value
Age. years	56.5 ± 7.1	54.8 ± 8.0	0.466
Female. n %	8 (38.1)	17 (77.3)	0.009
Systolic blood pressure, mm Hg	126 ± 12.1	119 ± 11.2	0.044
Diastolic blood pressure, mm Hg	79 ± 9.8	75 ± 9.9	0.307
Pulse pressure, mm Hg	47.5 ± 10.3	43.2 ± 7.9	0.138
Weight, kg	77 ± 12.7	71 ± 11.2	0.091
Body mass index, kg/m ²	26.9 ± 3.2	26.0 ± 3.4	0.418
Waist circumference, cm	93 ± 11.4	87 ± 12.4	0.103
Waist/height	0.55 ± 0.06	0.53 ± 0.08	0.315
Total cholesterol, mg/dL	228 ± 15.2	232 ± 16.2	0.333
HDL cholesterol, mg/dL	66.2 ± 14.8	70.1 ± 15.5	0.412
LDL cholesterol, mg/dL	130 ± 18.5	137 ± 18.5	0.239
Triglycerides, mg/dL	136 ± 40.1	126 ± 36.4	0.403
IFCC, mmol/mol	36.0 ± 4.4	37.5 ± 3.6	0.232
NGSP, %	5.45 ± 0.39	5.58 ± 0.34	0.283
eAG , mg/dL	110 ± 11.2	113 ± 9.7	0.284

Sequence 1: Treatment A followed by Treatment B.

Sequence 2: Treatment B followed by Treatment A.

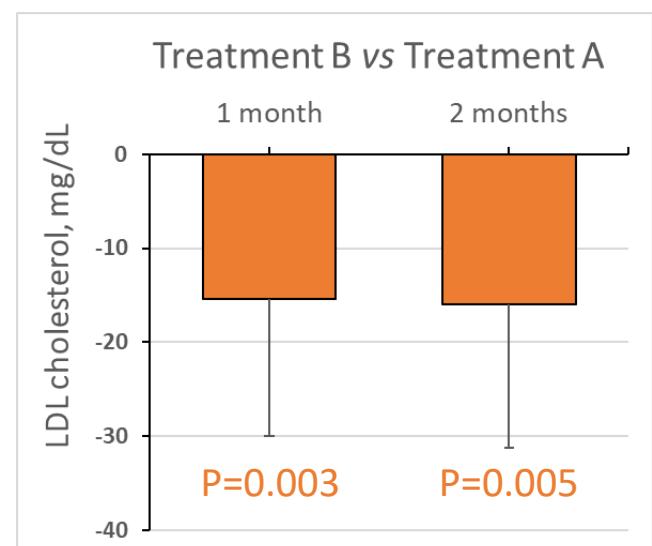
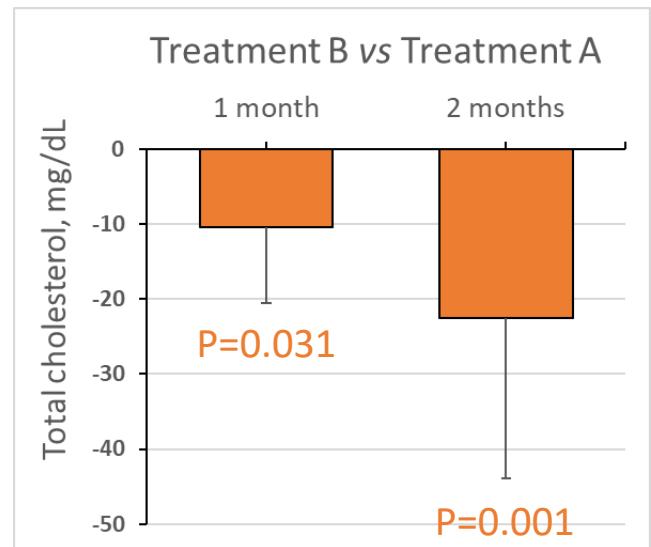
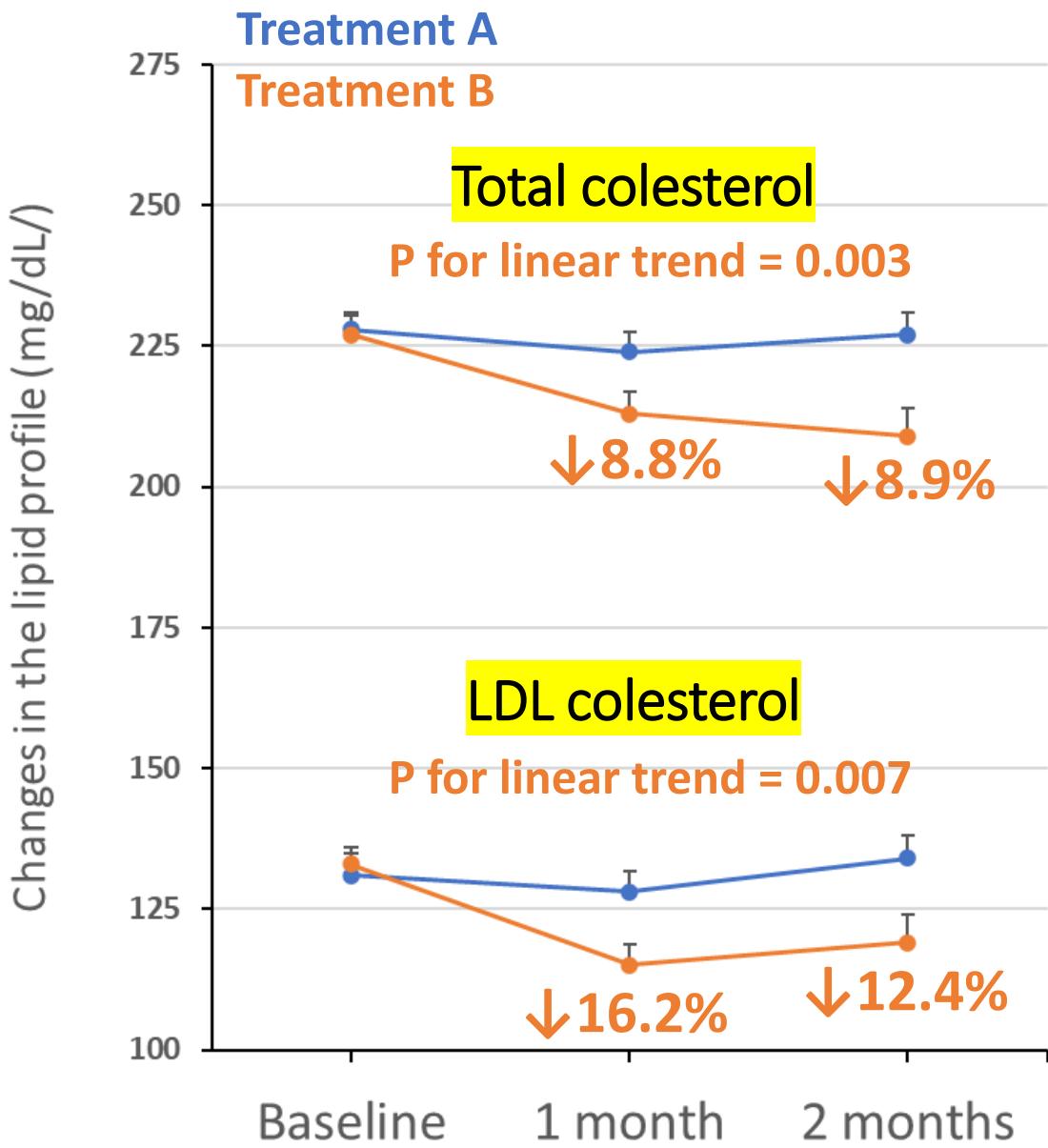
P value for ANOVA or χ^2 .

Results

CARDIOVASCULAR LIPID PROFILE

- **TRATAMIENTO A**
 - No changes were observed.
- **TRATAMIENTO B**
 - Linear decrease in total, LDL and non-HDL cholesterol concentrations both at 1 and 2 months of treatment.
 - The largest decreases were observed for LDL cholesterol ($\downarrow 16.2\%$ at 1 month and $\downarrow 12.4\%$ at 2 months).
 - No changes are seen in HDL cholesterol, although the total cholesterol/HDL cholesterol ratio decreased by 6.4% at 1 month.

Time-course for total and LDL cholesterol values



Results

VARIABLES ANTROPOMÉTRICAS

- **TRATAMIENTO A**

- There was a linear decrease in body weight ($\downarrow 0.79\%$) with no clinical significance reaching significance from baseline at 1 month of treatment, but no inter-treatment changes were observed.
- BMI decreased linearly ($\downarrow 1.06\%$) at 2 months of treatment, with the decrease being significant compared to the changes observed after treatment B.

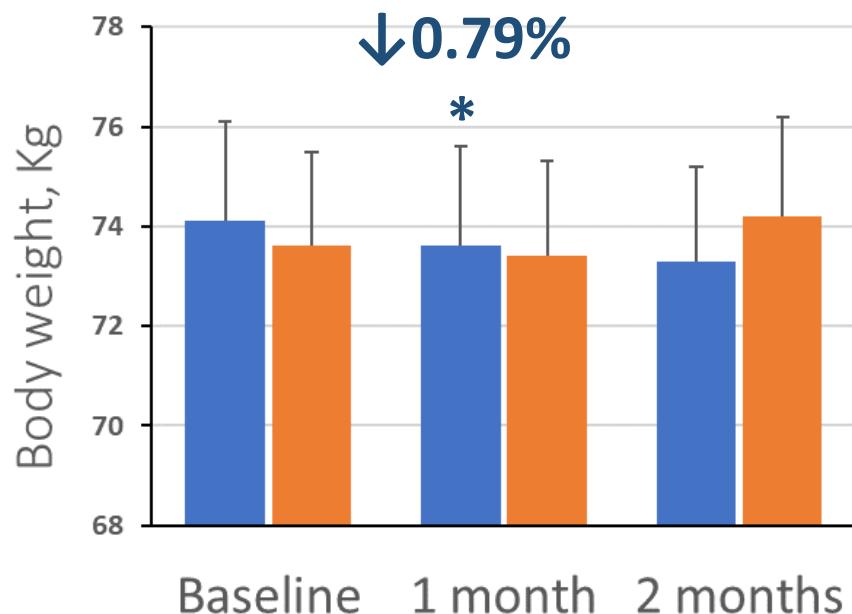
- **TRATAMIENTO B**

- No changes were observed.

Changes in total body weight and BMI values

Treatment A

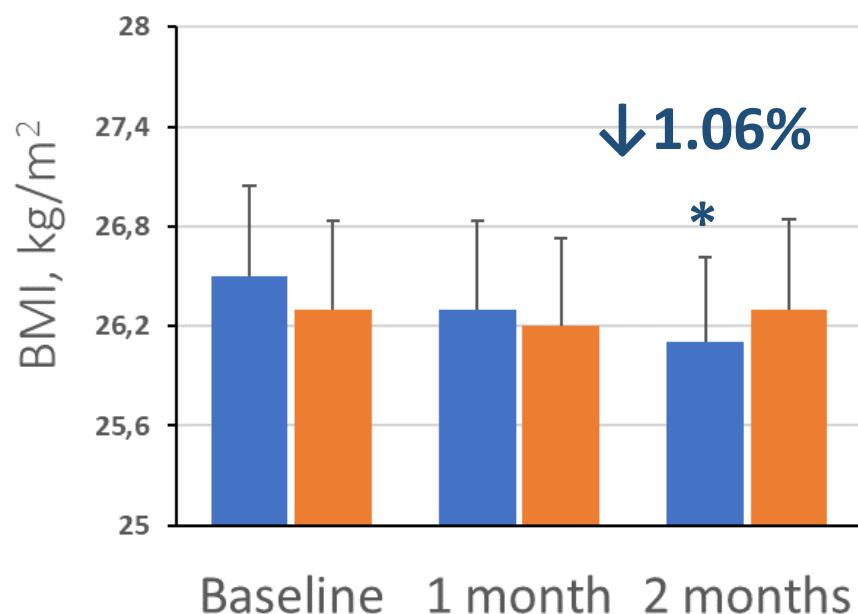
Treatment B



P for linear trend = 0.001

Treatment A

Treatment B



P for linear trend = 0.002

Resultados

PRESIÓN Y PULSO SANGUÍNEO

- TRATAMIENTO A
 - No changes were observed.
- TRATAMIENTO B
 - No changes were observed.

Resultados

Glycoside Hemoglobine

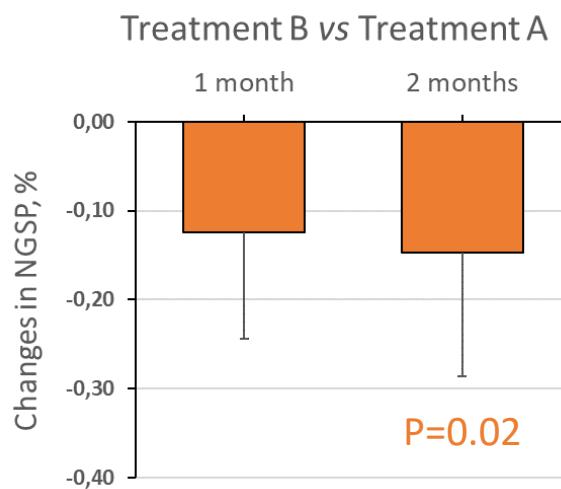
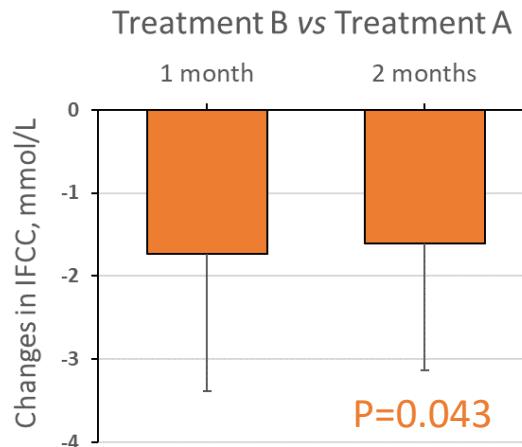
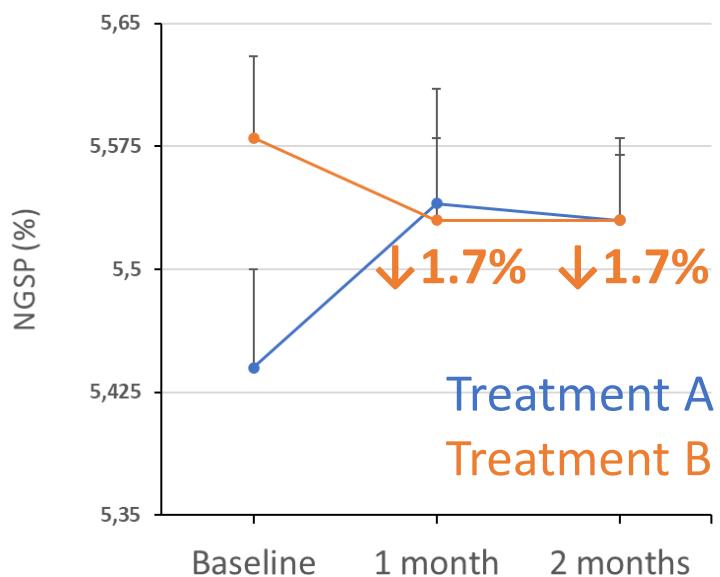
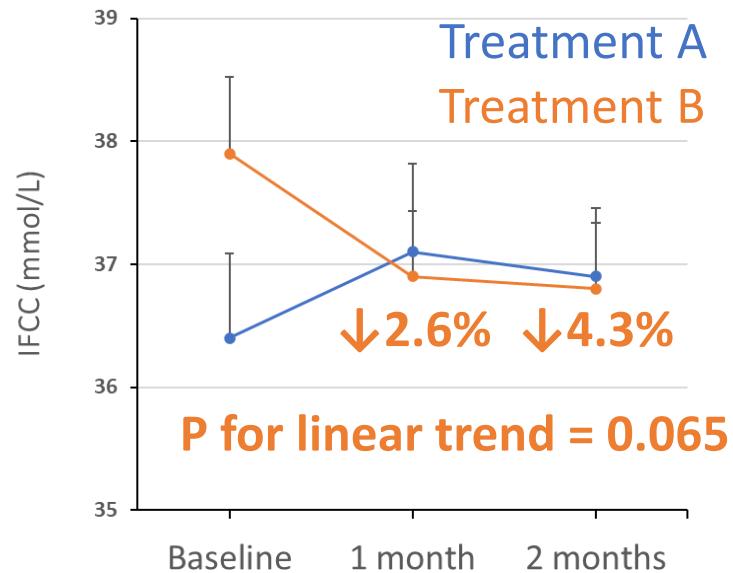
TREATMENT A:

- No changes were observed.

TREATMENT B:

- No intra-treatment changes were observed.
- When inter-treatment changes were assessed, IFCC and NGSP parameters decreased at 2 months after treatment B compared to the changes after treatment A.

Changes in Glucose Homeostasis Parameters



Conclusions

- Linear decrease in total cholesterol and LDL-cholesterol concentrations both at 1 month and 2 months of treatment B.
- The largest decreases were observed for LDL-cholesterol ($\downarrow 16.2\%$ at 1 month and $\downarrow 12.4\%$ at 2 months of treatment B).
- IFCC and NGSP parameters decreased at 2 months after treatment B compared to the changes produced by treatment A.