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Effect of a food supplement (Aquilea Colesterol®) on plasma total cholesterol and LDL cholesterol concentrations

Submission date
07/11/2018

Recruitment status
No longer recruiting

Registration date
20/02/2019

Overall study status
Completed

Last Edited
04/10/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
High levels of cholesterol in the blood can cause injury to the arteries, which may lead to a heart attack or stroke. Therefore, it is important to reduce these levels of cholesterol. One strategy for this is to improve lifestyle choices and use food supplements. Certain food supplements, which contain compounds called phytosterols or monacolin (from red rice), are already available on the market and have cholesterol-reducing effects.
This study aims to look at the effectiveness of a new food supplement, Aquilea Colesterol®, containing monacolin, phytosterols and two other cholesterol-reducing compounds (olive hydroxytyrosol and vitamin E) on the levels of cholesterol in the blood.

Who can participate?
Adults aged over 35 years with high cholesterol

What does the study involve?
Participants will be randomly allocated to one of two groups, either the intervention group or the control group. The intervention group will be given the Aquilea Colesterol® supplement, to be taken daily before their main meal for 90 days. The control group will be given a placebo supplement to take daily before their main meal for 90 days. All participants will be asked to attend clinical appointments just before beginning the study, after 4 weeks, and then for a final visit after 12 weeks, where they will be asked to complete a fasted blood test.

What are the potential risks and benefits of the study?
The possible benefit of participating is that individuals in the intervention group may have reduced cholesterol levels. The possible benefits of participating in the study are pain and bruising from the blood test, and potential mild gastrointestinal or muscular symptoms related to taking the food supplement.

Where is the study run from?
Outpatient clinic of the Department of Internal Medicine Service of Hospital Clinic of Barcelona (Spain)

When is the study starting and how long is it expected to run for?
September 2017 to February 2019

Who is funding the study?
Uriach Consumer Healthcare S.L. (Spain)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
02/2018

Study information

Scientific Title
Effect of Aquilea Cholesterol® on plasma cholesterol and lipid profile

Study objectives
The intake of Aquilea Cholesterol® food supplement (10 mg monacolin K, 1.5 g of phytosterols, 5 mg of olive hydroxytyrosol and 24 mg of vitamin E) is able to significantly reduce the concentration of total cholesterol and LDL cholesterol in patients with hypercholesterolemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Hospital Clínic of Barcelona, 07/02/2018, HCB/2017/0994

Study design
Interventional single-blinded randomised placebo-controlled parallel group pilot study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Hypercholesterolemia

Interventions
Participants will be randomly allocated to either the intervention or control group in a 1:1 ratio using a computer-generated random number sequence.
Participants allocated to the intervention group receive 10 mg monacolin K, 1.5 g phytosterols, 5 mg olive hydroxytyrosol and 24 mg vitamin E in a liquid stick (Aquilea Colesterol®). This food supplement should be taken daily for 90 days, preferably before the main meal.
Participants in the control group will receive 1 liquid stick of placebo per day, again to be taken daily for 90 days, preferably before the main meal.
There will be appointments at the baseline, and after 4 and 12 weeks.

Intervention Type

Other

Primary outcome measure
1. Lipid profile change, assessed at the baseline and after 12 weeks:
1.1. Total cholesterol, assessed using enzymatic procedures
1.2. HDL cholesterol, assessed by precipitation with phosphotungistic acid and magnesium chloride using the Advia 2400
1.3. Triglycerides, assessed using enzymatic procedures
1.4. LDL cholesterol, assessed using the following formula: LDL cholesterol = total cholesterol - HDL cholesterol - (triglycerides/5))
2. Change in oxidised LDLs, assessed using ELISA with the mAb-4E6 antibody at the baseline and after 12 weeks
3. Blood pressure, assessed using a validated semiautomatic oscilliometer at the baseline and after 4 and 12 weeks

Secondary outcome measures
1. Change in cardiovascular risk, assessed using the REGICOR score at the baseline and after 12 weeks
2. Change in biomarkers of systemic inflammation, assessed using ELISA at the baseline and after 12 weeks:
2.1. Plasma C-reactive protein (CRP)
2.2. Interleukin-6 (IL-6)

Overall study start date
01/09/2017

Completion date
20/02/2019

Eligibility

Key inclusion criteria
1. Aged 35-75 years
2. Low (<5%) or moderate (5-9%) coronary risk according to REGICOR risk tables
3. Total cholesterol values between 200-250 mg/dl according to previous analytical test
4. LDL cholesterol values >115 mg/dl without lipid-lowering treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
45

Total final enrolment

Key exclusion criteria
1. Using or previously used lipid-lowering treatment (statins, fibrates, resins, ezetimibe) and/or any other product with a lipid-lowering effect (red rice, plant sterols) in the previous 3 months
2. Indication for treatment with lipid-lowering drugs
3. Previous cardiovascular disease (myocardial infarction, angina, stroke, peripheral arterial disease)
4. High (10-14%) or very high (≥15%) coronary risk according to REGICOR risk tables
5. BMI ≥30 kg/m²

Date of first enrolment
01/05/2018

Date of final enrolment
15/10/2018

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clinic of Barcelona
C/Villarroel 170
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Sponsor information

Organisation
Uriach Consumer Healthcare S.L.

Sponsor details
Palau-Solità i Plegamans 08184 (Barcelona). Avinguda Camí Reial 51-57
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Sponsor type
Industry

ROR
https://ror.org/04jfxq686

Funder(s)

Funder type
Industry

Funder Name
Uriach Consumer Healthcare S.L.

Results and Publications

Publication and dissemination plan
Intention to publish in a high-to-medium impact peer-reviewed journal

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/04/2019	04/10/2019	Yes	No