

Effect of AlKylGlycerols on angiogenic and inflammatory factors in Obese individuals

Submission date
20/02/2013

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
04/04/2013

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
17/01/2019

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2006/2601/I/AGL2006-02031

Study information

Scientific Title
Effect of AlKylGlycerols on angiogenic and inflammatory factors in Obese individuals: a randomized double-blind cross-over clinical supplementation trial

Acronym

AKGO

Study objectives

A rich alkylglycerol (AKG) preparation will be more effective on inflammatory markers than a low AKG preparation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Clinical Research Ethical Committee of the "Institut de Recerca Hospital del Mar (IMIM)", 25 February 2008, ref: 2006/2601/I

Primary study design

Interventional

Study design

Randomized double-blind cross-over single centre clinical supplementation trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Community-dwelling obese participants with a body mass index (BMI) ≥ 30 kg/m² to ≤ 40 kg/m²

Interventions

Randomized, double-blind, cross-over, single centre clinical supplementation trial, in which 24 subjects (12 men and 12 women) will be randomised to one of two orders of administration of:

1. High alcoxylglycerol content (HAC: 20 mg AKG/ 6 ml olive oil)
2. Low alcoxylglycerol content (LAC: 10 mg AKG/ 6 ml olive oil)

There will be in three intervention periods of 3 weeks separated by 2-week wash-out periods avoiding shark oil or AKG supplements.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Alkylglycerol from olive oil

Primary outcome(s)

1. Inflammatory parameters measured at baseline and before and after each intervention:
 - 1.1. Serum immunoglobulins A, G, and M
 - 1.2. Complement 3(C3) and 4 (C4)
 - 1.3. Plasma interleukine-8 (IL8), monocyte chemotactic protein-1(MCP-1), and vascular endothelial growth factor (VEGF) .

Key secondary outcome(s)

Oxidative damage: Plasma lipids and lipid peroxides will be determined at baseline and 3 weeks after each intervention period.

Completion date

20/12/2012

Eligibility

Key inclusion criteria

1. Obese patients
2. Body mass index (BMI) ≥ 30 kg/m² to ≤ 40 kg/m²
3. Aged 20 - 60 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Intake of antioxidant supplement or acetylsalicylic acid or any other drug with established antioxidative properties
2. Athletes with physical activity (PA >3000 kcal/day in leisure-time
3. BMI <30 kg/m² or > 40 kg/m²)
4. Diabetes, multiple allergies, intestinal diseases
5. Any condition that limits the mobility of the subject making study visits impossible
6. Life threatening illness such as cancer or severe disease with a lowered expected 3 year survival
7. Any other disease or condition that would worsen the adherence to the measurements or treatment

Date of first enrolment

02/05/2012

Date of final enrolment

20/12/2012

Locations

Countries of recruitment

Spain

Study participating centre
IMIM Institut Hospital del Mar d'Investigacions Mèdiques
Barcelona
Spain
08003

Sponsor information

Organisation
Spanish Ministry of Economy and Competitiveness (Spain)

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Science and Technology (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2016	17/01/2019	Yes	No