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Effect of AlKylGlycerols on angiogenic and inflammatory factors in Obese individuals

Submission date	Recruitment status
20/02/2013	No longer recruiting
Registration date	**Overall study status**
04/04/2013	Completed
Last Edited	**Condition category**
17/01/2019	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Committe of the "Institut de Recerca Hospital del Mar (IMIM)", 25 February 2008, ref: 2006/2601/I

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 15 women) will be randomised to one of two orders of administration of:
1. High alcoxyglycerol content (HAC: 20 mg AKG/ 6 ml olive oil)
2. Low alcoxyglycerol 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 measure
1. Inflammatory parameters measured at baseline and before and after each intervention:
1.1. Serum inmunoglobulines 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) .

Secondary outcome measures
Oxidative damage: Plasma lipids and lípid peroxides will be determined at baseline and 3 weeks after each intervention period.

Overall study start date
02/05/2012

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

Age group
Adult

Sex
Both

Target number of participants
24

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)

Sponsor details
MINECO
Former Spanish Ministry of Science and Technology
Secretaría General de Innovación
Albacete, 5
Madrid
Spain
28027

Sponsor type
Government

Website
http://www.mineco.gob.es

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Science and Technology (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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