

Effect of AlKylGlycerols on angiogenic and inflammatory factors in Obese individuals

Submission date 20/02/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/01/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Maria Isabel Covas

Contact details
IMIM Institut Hospital del Mar d'Investigacions Mèdiques
Cardiovascular Risk and Nutrition Group
Dr. Aiguader, 88
Barcelona
Spain
08003

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 Committee 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 12 women) will be randomised to one of two orders of administration of:

1. High alkoxyglycerol content (HAC: 20 mg AKG/ 6 ml olive oil)
2. Low alkoxyglycerol 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 immunoglobulins A, G, and M

1.2. Complement 3 (C3) and 4 (C4)

1.3. Plasma interleukin-8 (IL8), monocyte chemotactic protein-1 (MCP-1), and vascular endothelial growth factor (VEGF) .

Secondary outcome measures

Oxidative damage: Plasma lipids and lipid 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