

# Effect of AlKylGlycerols on angiogenic and inflammatory factors in Obese individuals

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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

### **Study design**

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

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Community-dwelling obese participants with a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> to  $\leq 40$  kg/m<sup>2</sup>

### **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 immunoglobulines 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)  $\geq 30$  kg/m<sup>2</sup> to  $\leq 40$  kg/m<sup>2</sup>
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/m<sup>2</sup> or > 40 kg/m<sup>2</sup>)
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?
<a href="#">Results article</a>	results	01/06/2016	17/01/2019	Yes	No