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Effect of moderate wine consumption on the clinical symptoms of patients with inflammatory bowel disease

Submission date
06/06/2021

Recruitment status
No longer recruiting

Registration date
07/09/2021

Overall study status
Completed

Last Edited
14/06/2022

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Previous studies have shown that moderate wine consumption has a beneficial effect on the intestinal function of healthy people. Those benefits include modulation of colonic microbiota (gut microbes) and improved inflammation markers. Many of these benefits are attributed to wine polyphenols, which are found in large quantities in grapes and, therefore, in wine. With this background, the aim of this study is to assess the effect of moderate wine consumption in patients with inflammatory bowel disease, a group of disorders in which the intestines become inflamed, including ulcerative colitis.

Who can participate?
Patients with ulcerative colitis who have not taken antibiotics in the last 6 months or follow restrictive diets

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. Participants begin with a two-week period in which they consume a diet low in polyphenols, after which the intervention group drink 250 ml of wine per day for 4 weeks. The control group participants continue with the low polyphenol diet. Markers of ulcerative colitis are measured using blood tests at the start and the end of the study.

What are the possible benefits and risks of participating?
The expected results are a reduction in markers of ulcerative colitis such as fecal calprotectin and beneficial changes in the intestinal microbiota in patients in the intervention group, as well as an improvement in quality of life and symptoms of the disease.

Where is the study run from?
Institute of Food Science Research (Spain)

When is the study starting and how long is extended to run for?
September 2017 to December 2019

Who is funding the study?
Spanish Ministry of Science and Innovation (Spain)

Who is the main contact?
1. Dr M. Victoria Moreno-Arribas, victoria.moreno@csic.es
2. Dr Begoña Bartolomé

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AGL2015-64522-C2-1-R

Study information

Scientific Title
Moderate wine consumption and digestive function: intestinal microbiota, metabolic functionality and effect on the clinical symptoms of patients with inflammatory bowel disease

Acronym
VinEII

Study objectives
Wine, in particular red wine, is a source of dietary polyphenols which possesses a unique combination of phenolic structures (mainly flavonoids, but also non-flavonoids). Previous studies have shown an effect of moderate wine consumption in the modulation of the intestinal microbiota and specifically in the intestinal inflammatory response of healthy individuals. It is hypothesized that moderate and regular intake of red wine may modulate oral and gut microbiota in inflammatory bowel disease (IBD) patients, maintaining and even decreasing the proportions of different disease-related pathogenic groups, promoting a profile more similar to that observed in healthy conditions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/10/2017, Ethics Committee of the 'Hospital Universitario La Paz' (261, Castellana Street, Madrid, 28046, Spain; +34 (0)917277413; ceic.hulp@salud.madrid.org) and rhe Spanish National Research Council Ethics Committee (117, Serrano Street, Madrid, 28006, Spain; +34 (0) 915681494; subcomitedebioetica@csic.es), ref: not applicable

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
People were allocated randomly at the hospital to the control or intervention group by lottery until occupying the places of the group.

The study consists of two periods: a wash-out period (2 weeks in which the participants will not eat foods rich in polyphenols) and an intervention period (4 weeks in which the volunteers of the intervention group will drink 250 ml/day of red wine and the volunteers of the control group will continue with the same diet as in the wash-out period).
On the first day after the washout period and the last day of the intervention period, all of the participants go to the hospital after at least 10 hours of fasting. Then, they deliver a sample of

faeces taken as recent to this moment as possible (in a stool collection tube introduced in an anaerobic plastic zip bag) and a sample of 24 h urine (in a sterile bottle). Then, they spit into a 15 ml Falcon sterile tube to obtain at least 3 ml of saliva. Also, they complete a questionnaire on quality of life. A sample of blood is taken by a specialist.

Intervention Type
Supplement

Primary outcome measure
Markers of ulcerative colitis such as fecal calprotectin, iron, ferritin, C-reactive protein and white and blood cells measured by routine blood tests at initial and end treatment point (4 weeks)

Secondary outcome measures
1. Quality of life measured by quality of life questionnaires (IBDQ-32) at initial and end treatment point (4 weeks)
2. Microbial phenolic metabolites in faeces and urine measured by ultra-high-performance liquid chromatography–electrospray ionization–tandem mass spectrometry (UHPLC-ESI-MS/MS) at initial and end treatment point (4 weeks)
3. Short and medium-chain fatty acids in faeces measured by solid-phase microextraction gas chromatography-mass spectrometry (SPME-GC-MS) at initial and end treatment point (4 weeks)
4. Composition, abundance and diversity of the faecal microbiota measured by sequencing the V3-V4 region of ribosomal DNA from fecal samples and metagenomic analysis at initial and end treatment point (4 weeks)

Overall study start date
01/09/2017

Completion date
20/12/2019

Eligibility

Key inclusion criteria
Patients diagnosed with mild or moderate ulcerative colitis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
1. Antibiotic intake up to 6 months before the study
3. Type I diabetes, endocrine and gastrointestinal disorders
4. Addiction to drugs or alcohol
5. Restrictive diets (vegetarians, vegans)

Date of first enrolment
03/05/2018

Date of final enrolment
27/05/2019

Locations

Countries of recruitment
Spain

Study participating centre
Instituto de Investigación en Ciencias de la Alimentación (CIAL). Spanish National Research Council (CSIC)
Nicolás Cabrera Street, 9
Madrid
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Study participating centre
Hospital Universitario Infanta Sofía
Europe Street, 34
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Sponsor information

Organisation
Institute of Food Science Research

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Sponsor type
Research organisation

Website
http://www.cial.uam-csic.es/en/

ROR
https://ror.org/04dgb8y52

Funder(s)

Funder type
Government

Funder Name
Ministerio de Ciencia e Innovación

Alternative Name(s)
CienciaGob, Ministerio de Ciencia e Innovación de España, Ministry of Science and Innovation, Spanish Ministry of Science and Innovation, Ministry of Science and Innovation of Spain, Spain, Ministry for Science and Innovation, Ministeri de Ciència i Innovació, MCIN, MICINN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication of at least two research articles in high-impact peer-reviewed journals. At the moment no protocol is available.

Intention to publish date
20/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from M. Victoria Moreno-Arribas (victoria.moreno@csic.es).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/05/2022	14/06/2022	Yes	No