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Effect of resveratrol capsules on knee osteoarthritis symptoms and specific markers of joint breakdown

Submission date
21/08/2020

Recruitment status
No longer recruiting

Registration date
09/09/2020

Overall study status
Completed

Last Edited
06/10/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition that causes joints to become painful and stiff. The treatment of knee osteoarthritis still remains a challenge. There is a need not only for effective and safe treatments but also for specific and reliable biomarkers that would help to observe both the progression of the disease and treatment effectiveness. Resveratrol extracted from Polygonum cuspidatum is a natural chemical that is found in grape skin, berries and peanuts. Pre-clinical studies provided evidence on the effectiveness of resveratrol in reducing degenerative articular damage. Recently a clinical study demonstrated the effectiveness of resveratrol as an add-on treatment in alleviating pain and reduction of inflammatory biomarkers. However, there are no clinical trials to date to determine the effectiveness of resveratrol as a treatment in articular disorders particularly in knee osteoarthritis and investigating biomarkers of cartilage breakdown. The aim of this study is to investigate the effects of resveratrol (as an oral capsule) in patients with mild or moderate knee osteoarthritis on the blood levels of specific biomarkers of osteoarthritis and on the evaluation of pain.

Who can participate?
Patients with mild to moderate osteoarthritis

What does the study involve?
The study will involve a 12-week of administration of oral resveratrol (500 mg/day in a single dose). A rescue medication (500 mg of acetaminophen and up to four tablets per day) will be given to the patients for non-tolerated pain they will experience during the study period. Specific biomarkers of osteoarthritis are measured before treatment (at day 0) and after 90 days of treatment.

What are the possible benefits and risks of participating?
The expected benefit of the current study is providing a new approach from a natural source Polygonum cuspidatum for the treatment of knee OA with fewer side effects and more regeneration of the cartilage. No risks are expected unless there might be a non-remarkable result due to the short duration of the study.

Where is the study run from?
Teaching Hospitals of Sulaimani City (particularly Shar Teaching Hospital) (Iraq)

When is the study starting and how long is it expected to run for?
December 2019 to October 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Assistant Professor Dr Bushra Hassan Marouf
bushra.marouf@univsul.edu.iq

Contact information

Type(s)
Public

Contact name
Dr Bushra Marouf

ORCID ID
https://orcid.org/0000-0002-7658-9013

Contact details
Sulaimani-Old Campus
Sulaimani
Iraq
00964
+964 (0)7701562796
bushra.marouf@univsul.edu.iq

Type(s)
Scientific

Contact name
Dr Bushra Marouf

ORCID ID
https://orcid.org/0000-0002-7658-9013

Contact details
Sulaimani-Old Campus
Sulaimani
Iraq
00964
+964 (0)7701562796
bushra.marouf@univsul.edu.iq

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A pilot clinical study of the effect of resveratrol on the serum level of Coll 2-1 and Aggrecan biomarkers in patients with knee osteoarthritis; a non-randomized open-labelled clinical trial

Acronym
APCERCA

Study objectives
Stated hypothesis: use of resveratrol (500 mg/day) alone may have a significant effect on the improvement of pain and specific biomarkers (Coll 2-1 and aggrecan) in patients with knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2020, Ethical Committee of College of Medicine, University of Sulaimani (Iraq-Kurdistan Region, Sulaimani, Street 27- Zone 209, Iraq; +964 (0)53 3270924; kosar.ali@univsul.edu.iq), ref: 180

Study design
Pilot clinical study of non-randomized non-controlled open-labelled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
This is a single-arm non-randomized non-controlled open labelled clinical trial. The study will be a 12-week of administration of oral resveratrol (500 mg/day in a single dose) alone in patients with mild to moderate osteoarthritis. A rescue medication (500 mg of acetaminophen and up to four tablets per day) will be given to the patients for non-tolerated pain they experience during the study period. Resveratrol is a natural phytoalexin that is found in the grape skin, berries and peanuts.

Intervention Type

Supplement

Primary outcome(s)
1. Specific biomarkers of osteoarthritis (Coll 2-1 and Aggrecan) measured using enzyme-linked immunosorbent assay (ELISA) kit according to the manufacturer instructions before treatment (at day 0) and after 90 days of treatment.
2. Biomarkers of inflammation including TNF-α, IL-1β, IL-6 (measured using ELISA kit according to the manufacturer instructions) and hsCRP and the complement system (measured by spectrophotometry utilizing ready-made kits and Roche/Hitachi cobas c systems) measured at baseline at Day 0 (pre-treatment) and at day 90 (post treatment)
3. Standard haematological profile (measured utilizing the Swelab Alfa Plus system) and both liver and kidney functions markers (liver and kidney function tests), and lipid profiles measured spectrophotometrically using the clinical chemistry analyzer Cobas c 311 and ready-made kits according to the manufacturer's recommendations for evaluating safety and tolerability of resveratrol at baseline and at the end of the treatment

Key secondary outcome(s))
Symptoms of osteoarthritis measured using the adopted scoring systems of visual analogue scale for pain (VAS) and Knee injury and Osteoarthritis Outcome Score (KOOS) at baseline (day 0), 1, 2 and 3 months

Completion date
01/10/2020

Eligibility

Key inclusion criteria
Mild to moderate OA at both screening and baseline visits, as defined by the up-to-date revised American College of Rheumatology (ACR) criteria for diagnosis of knee OA

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
35

Key exclusion criteria
1. Patients with a history of rheumatoid arthritis, gout, severe ischaemic heart disease, heart failure, hepatic failure, renal failure

2. Consumption of non-steroidal anti-inflammatory drugs or corticosteroid drugs within 4 weeks of study, intra-articular injection within 3 months prior to the study recruitment
3. Pregnant or desire to become pregnant, or lactating women

Date of first enrolment
10/01/2020

Date of final enrolment
10/03/2020

Locations

Countries of recruitment
Iraq

Study participating centre
University of Sulaimani
College of Pharmacy with Shar Teaching Hospital
46001 Sulaymaniyah
Kurdistan Region
Sulaimani
Iraq
00964

Sponsor information

Organisation
University of Sulaimani

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Assistant Professor Dr Bushra Hassan Marouf (bushra.marouf@univsul.edu.iq).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/11/2021	16/11/2021	Yes	No
Protocol file			06/10/2022	No	No