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Pycnogenol (maritime pine bark extract) in osteoarthritis

Submission date
07/10/2015

Recruitment status
No longer recruiting

Registration date
08/10/2015

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis, affecting millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, which can cause stiffness, pain and a reduction in a person's range of movement. The knee is the most common joint to be affected by OA, and in severe cases, surgery may be the only treatment that can provide patients with relief. A knee arthroplasty, also known as knee replacement surgery, is recommended if the pain from OA is so severe that it is causing disability. In this operation, the diseased cartilage and bone is removed from the surface of the knee joint and replaced with a man-made surface of metal or plastic. This can happen on one side (partial) or both sides (total) of the knee joint, depending on how severe the damage is. Pycnogenol is the trade name of a dietary supplement made from French maritime pine bark extract. Previous studies have shown that it can help to relieve pain and joint stiffness in knee OA patients. Currently little is known about how it does this and whether components of the drug spread through the joints. The aim of this study is to find out how Pycnogenol works in patients with OA and how its components are spread throughout the body.

Who can participate?
Adults with severe knee osteoarthritis who are having knee replacement surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive 200mg of Pycnogenol twice a day for three weeks before they are due to have their knee replacement surgery. Those in the second group do not receive any additional treatment in the three weeks leading up to their surgery. Blood samples are collected from all patients at the start of the study, 1-2 days before their surgery and just before/during their surgery, and joint fluid is taken on the day of the surgery. The blood and joint fluid are tested for markers that play a role inflammation and cartilage destruction of the joints.

What are the possible benefits and risks of participating?
There are no direct benefits or risks of participating in the study.

Where is the study run from?
Orthopedic Center for Musculoskeletal Research (Germany)

When is the study starting and how long is it expected to run for?
October 2012 to September 2014

Who is funding the study?
Horphag Research LTD (Cyprus)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
1. It is possible to detect constituents and/or metabolites of Pycnogenol in serum, blood cells and synovial fluid of patients after ingestion of the extract
2. Constituents and/or metabolites of Pycnogenol influence inflammatory and cartilage metabolism markers in osteoarthritis patients

Study objectives
After ingestion of Pycnogenol, components and/or metabolites of the extract are distributed into serum, blood cells and synovial fluid. Bioactive compounds in serum and synovial fluid exhibit molecular effects on key catabolic and inflammatory markers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of the Medical Faculty of the University Würzburg, 21/12/2011, ref: 248 /11

Primary study design
Interventional

Study design
Single-centre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Patients were randomized into two groups using a computer-generated randomization list which was not accessible to the physicians and nurses who were involved in the patient care and management. Half of the study participants (n= 15) were assigned to the treatment group receiving 200 mg of the French maritime pine bark extract Pycnogenol® per day (twice daily two capsules with each 50 mg) over three weeks prior to the planned surgery. The control group comprised of 15 patients who received no Pycnogenol®.

Blood samples from each study participant were collected before oral intake of Pycnogenol® (V1, basal value); during the intake, approximately 1-2 days before the surgery (V2); and during or shortly before knee surgery (V3), about 12 h after the last dose of Pycnogenol®. On the day of the surgery residual knee cartilage and synovial fluid were also collected. There was no further follow-up.

Intervention Type
Supplement

Primary outcome(s)

Detection and quantification of constituents and/or metabolites of Pycnogenol in serum, blood cells (before and after intake of Pycnogenol; V1, V2, V3) and synovial fluid (at the time of knee surgery, V3) of patients.

Key secondary outcome(s)
Measurement of markers of inflammation and cartilage metabolism in the patient's serum, blood cells (before and after intake of Pycnogenol; V1, V2, V3) and synovial fluid (at the time of knee surgery, V3) of patients, e.g. MMP-3, MMP-13, IL-1β, ADAMTS-5.

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Severe knee osteoarthritis according to the Western Ontario and McMaster Universities Arthritis Index (WOMAC) score
3. Scheduled for an elective arthroplasty (Kellgren-Lawrence grade III-IV)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Taking Non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids within the past four weeks
2. Currently received a therapy with anti-coagulants
3. Tested positive for HIV, HCV or HCB
4. Have had a previous or current infection of the affected knee joint

Date of first enrolment
01/09/2012

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Germany

Study participating centre
Orthopedic Center for Musculoskeletal Research
Department of Orthopedics
Brettreichstraße 11
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Study participating centre
Institute of Pharmacy and Food Chemistry (Institut für Pharmazie und Lebensmittelchemie)
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Sponsor information

Organisation
Horphag Research LTD

ROR
https://ror.org/003n34405

Funder(s)

Funder type
Industry

Funder Name
Horphag Research LTD

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/12/2017		Yes	No