ISRCTN10754119 https://doi.org/10.1186/ISRCTN10754119

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?
1. Professor Petra Högger (Scientific)
petra.hoegger@uni-wuerzburg.de
2. Dr Lothar Seefried (Public)
l.seefried.klh@uni-wuerzburg.de

Contact information

Type(s)
Scientific

Contact name
Prof Petra Högger

Contact details
Institut für Pharmazie und Lebensmittelchemie
Am Hubland C7
Würzburg
Germany
97074
+49 (0)931 318 5468
petra.hoegger@uni-wuerzburg.de

Type(s)
Public

Contact name
Dr Lothar Seefried

Contact details
Orthopedic Center for Musculoskeletal Research, Department of Orthopedics
Brettreichstraße 11
Würzburg
Germany
97074
+49 (0)931 8030
l.seefried.klh@uni-wuerzburg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Single-centre randomised controlled 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 to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/05/2011

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
30

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
Würzburg
Germany
97074

Study participating centre
Institute of Pharmacy and Food Chemistry (Institut für Pharmazie und Lebensmittelchemie)
Am Hubland C7
Würzburg
Germany
97074

Sponsor information

Organisation
Horphag Research LTD

Sponsor details
Karaiskaki 38
Kanika Alexander Court
1st floor, Flat/Office 113CD
P.C. 3032
Limassol
Cyprus
3032

Sponsor type
Industry

Website
http://www.pycnogenol.com/

ROR
https://ror.org/003n34405

Funder(s)

Funder type
Industry

Funder Name
Horphag Research LTD

Results and Publications

Publication and dissemination plan
Two publications are planned, one reporting the results of the analysis of componetns and metabolites in serum, blood cells and synovial fluid (pharmacokinetic aspect), the other covering the results of the relative gene expression of cartilage homeostasis markers as well as inflammatory and cartilage metabolism mediators in serum and synovial fluid samples (cellular pharmacodynamic aspect).

Intention to publish date
01/01/2016

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