ISRCTN17230715 https://doi.org/10.1186/ISRCTN17230715

A dietary supplement for the management of patients with back pain

Submission date
26/04/2021

Recruitment status
No longer recruiting

Registration date
28/04/2021

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Lumbar osteochondrosis is a disease of the lumbar (lower) spine caused by wear and tear on the intervertebral discs, vertebrae, vertebral joints or ligaments. Treatment is usually through pain and exercise therapy. The aim of this study is to investigate the 3-month intake of a dietary supplement as an accompanying measure to medical treatment. The food supplement, which has been sold in pharmacies for several years, is a combination of certain nutrients (collagen type II, hyaluronic acid, glucosamine, bamboo extract, L-lysine, and vitamin C) that occur naturally in the intervertebral disc and are intended to improve back pain or at least contribute to the maintenance of the spinal column function.

Who can participate?
Patients aged 18 to 75 with back pain, diagnosed with painful osteochondrosis

What does the study involve?
Participants are randomly allocated to take supplement or placebo (dummy) capsules daily with a glass of water (2 capsules during breakfast and 2 capsules during dinner) for 3 months. The research assistant contacts participants at least once during the 3-month intervention period to provide support if needed. Participants complete questionnaires and undergo MRI scans at the start of the study and after the 3-month supplementation.

What are the possible benefits and risks of participating?
The benefits of participating include being provided with free supplements for 3 months. The risks are very minimal and include potential side effects of the supplement's ingredients.

Where is the study run from?
The study is run by the Department of Nutritional Sciences, the University of Vienna with the OrthoCare and HealthPi Medical Center (Vienna, Austria)

When is the study starting and how long is it expected to run for?
April 2016 to December 2021

Who is funding the study?
The Austrian Research group for Orthopedic Medicine (AURROM) (Austria)

Who is the main contact?
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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
Nil known

Study information

Scientific Title
A dietary supplement for the management of patients with lumbar osteochondrosis

Acronym
NutS4IVDs

Study objectives
A 3-month supplementation with a combination of specific dietary compounds including collagen type II, hyaluronic acid, glucosamine, bamboo extract, L-lysine, and vitamin C improve pain and function in the management of patients with lumbar osteochondrosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2017, ethics committee of the Medical University of Vienna (Borschkegasse 8b /E06, 1090 Vienna, Austria; +43 (1)40400 21360; ethik-kom@meduniwien.ac.at), ref: 1998/2016; protocol version 1.0

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Lumbar osteochondrosis

Interventions
Randomization is performed in a 1:1 ratio in blocks of 10 and is generated via http://www.randomization.com. All packages will be labelled with the randomization number.

Active intervention:
The active study dietary supplement capsules (Vertebene Bandscheibenkapseln, Natural Products & Drugs GmbH, Spital a.d. Drau, Austria) are composed of a mix of the following nutritional compounds: collagen hydrolysate, collagen type II, mucopolysaccharides, hyaluronic acid, glucosamine, bamboo extract, L-lysine hydrochloride, and vitamin C.

Comparator:
The same company (Natural Products & Drugs GmbH, Austria) producing the active capsules provide the control capsules (placebos). Cellulose is used as an inactive filler for the placebo capsules.

Patients in both groups are advised to take 2 x 2 capsules daily with a glass of water (2 capsules during breakfast and 2 capsules during dinner) for 3 months. The research assistant contacts participants at least once during the 3-month intervention period to provide support if needed. At baseline and follow-up (once after the intervention), all participants are asked to complete the subjective questionnaire and the lumbar magnetic resonance image are collected.

Intervention Type
Supplement

Primary outcome measure
Pain and function measured using the Oswestry Disability Index (ODI) at baseline and after the 3-month intervention

Secondary outcome measures
1. Intervertebral disc distances (IVDD) measured using magnetic resonance images (MRI) at baseline and after the 3-month intervention
2. Pain measured using the visual analogue scale (VAS) at baseline and after the 3-month intervention
3. Quality of life measured using the short form 12 (SF-12) at baseline and after the 3-month intervention
4. Nutritional status measured with a 60-item Food frequency questionnaire (FFQ) at baseline and after the 3-month intervention
5. Physical activity measured with the Global Physical Activity Questionnaire (GPAG) at baseline and after the 3-month intervention
6. Global satisfaction with the interventional procedure measured on a Likert scale with five categories ranging from very satisfied (4 points) to not satisfied at all (0 points) at baseline and after the 3-month intervention

Overall study start date
26/04/2016

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Female and male patients aged between 18 and 75 years of age
2. Patients with symptomatic (VAS ≥4) MRI-confirmed lumbar osteochondrosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
50

Key exclusion criteria
1. Patients with asymptomatic (VAS ≤ 3) MRI-confirmed (Pfirrmann grades 1 and 5 lumbar osteochondrosis
2. Patients with pathologies including
2.1. Rheumatoid osteoarthritis
2.2. Fibromyalgia
2.3. Scoliosis
2.4. Neurological deficit
2.5. Morbid adiposity (body mass index, BMI ≥40)
2.6. Any other current or past clinically significant disease (comorbidity) that, in the opinion of the orthopaedic consultant, might confound the results of the study or poses an additional risk to the subject during participation in the study (e.g. renal, neoplastic, epigastric disease)
3. Previous surgeries of intervertebral disc(s), hip(s)
4. Allergies/intolerances against any component of the dietary supplement (e.g. shellfish)
5. Pregnant or lactating women
6. Not fluent (read/understand) in German (consent, questionnaires, and study forms are in German)
7. Not able to undergo MRI (e.g. claustrophobia, pacemaker)

Date of first enrolment
01/03/2017

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
Austria

Study participating centre
HealthPi Medical Center
Wollzeile 1
Vienna
Austria
1010

Sponsor information

Organisation
Austrian Research group for Regenerative and Orthopedic Medicine (AURROM)

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Austrian Research group for Regenerative and Orthopedic Medicine (AURROM)

Funder Name
All dietary supplements and placebos are donated by Natural Products & Drugs GmbH; however, they will not be involved in any other part of the study.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The study protocol will be available after it has been published.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/08/2024	04/10/2024	Yes	No