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Developing an algorithm for classification of people with sciatica in the Greek health system

Submission date
05/02/2020

Recruitment status
No longer recruiting

Registration date
10/02/2020

Overall study status
Completed

Last Edited
07/03/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A large percentage of people with low back pain, also complain of sciatica. Sciatica is pain that spreads down one leg from the lower back and buttocks. Usually, the pain extends below the knee sometimes to the foot and there may also be tingling or numbness of the skin.

The cause of sciatica varies and may be due to problems with the spine. Finding the cause of sciatica often involves the use of expensive imaging methods (magnetic resonance imaging) which can be misleading. Therefore research is increasingly focused on exploring more effective evaluation tools to categorize these patients with the aim of selecting the most appropriate technique for their treatment.

In the international physiotherapy community, some evaluation tools for sciatica have been proposed, but in Greece, no such study has ever been performed. This study aims to collect knowledge of the evaluation and categorization of patients with sciatica, with the hope of enhancing the quality of physiotherapy services and alleviating the symptoms of suffering patients.

Who can participate?
Adults aged 18 and above, who are referred from their spine specialist with sciatica or suspected sciatica. They must also have a mobile phone that can receive and send SMS texts or have access to a landline telephone, they must be willing to participate and the must understand to read and speak Greek

What does the study involve?
Patients referred with sciatica will be assessed from a specialist physiotherapist in order to categorize their symptoms and develop a method for classification in the greek health system

What are the possible benefits and risks of participating?
There are no risks involved in this research. The patients will not receive any treatment only standard clinical assessments and they will be asked to fill in some self-reported questionnaires

Where is the study run from?
The University of West Attica (Greece)

When is the study starting and how long is it expected to run for?
February 2019 to December 2022

Who is funding the study?
The University of West Attica (Greece)

Who is the main contact?
1. Nikolaos Kontakiotis PhD Cand, MSc, MMACP, MCSP
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2. Prof. Georgios Gioftsos
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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
2604 4/2/2020

Study information

Scientific Title

Investigation into the distinct clinical characteristics of people with sciatica in order to develop an algorithm for their classification in the Greek health system

Acronym
Sciatica classification algorithm

Study objectives
Can the evaluation tools of sciatica develop a reliable categorization algorithm for patients suffering from sciatica in order to find better treatment in the primary Greek health system?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/06/2020, Ethics and Deontology Committee of the University of West Attica (Agiou Spiridonos 28, Egaleo, Athens, Greece, 12243; +30 (0)2105387294; adeltsidou@uniwa.gr), ref: 2604 4/2/2020, protocol number: 38313

Study design
Single-blinded, observational epidemiological multicentre study for algorithm development

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Community

Study type(s)
Diagnostic

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
Sciatica

Interventions
All patients will be informed about the purpose of this study by an information sheet and about the assessment that they will get for their symptoms. Before the start of the assessment, they will sign a consent form, ensuring their participation and anonymity. Their anonymity due to sensitive personal data will be secured during the study, but also after the publication of the results. Finally, they will be allowed to withdraw from the survey at any time they wish. Patients referred with sciatica from spine specialists will be examined by a specialist musculoskeletal physiotherapist. The specialist musculoskeletal physiotherapist will be responsible for

conducting all evaluation tests and recording all data. Initially, each patient will be evaluated to determine whether or not they will be accepted into the study by answering some simple questions that will confirm the study's eligibility criteria.

The assessment will have three parts. The order will be randomized in the below three parts:
1. Questionnaires
2. Neurologic examination
3. Neurodynamics
Patients will perform all three parts of the assessment with random order.

Questionnaires will be completed in the presence of the specialist musculoskeletal physiotherapist to avoid any confusion. The specialist musculoskeletal physiotherapist will perform the neurological examination and quantitative aesthetic tests with the tool kit to draw conclusions about the neurological dysfunction. The third part of the assessment will be the performance of the neurodynamics test in order to evaluate the symptoms of the patients. All data will be recorded in detail and carefully to be statistically analyzed when the necessary number of patients is collected in order to develop an algorithm subgrouping these patients to low, medium and high risk in the Greek health system.

Intervention Type
Other

Primary outcome measure
Development of an algorithm to categorize patients as low, medium and high-risk based on their sciatica symptoms assessed by questionnaires, neurologic examination, and neurodynamics evaluation at baseline without follow up

Secondary outcome measures
1. Disability is measured using the Roland Morris Disability Questionnaire at baseline at baseline without follow up
2. Overall impact of sciatica symptoms is measured using the Sciatica Bothersomeness Index at baseline without follow up
3. Fear of movement is measured using Fear-Avoidance Beliefs Questionnaire at baseline without follow up
4. Anxiety and depression are measured using Hospital Anxiety and Depression Scale at baseline without follow up
5. Risk of poor outcome is measured using STarT Back Tool at baseline without follow up
6. Neuropathic pain scales are measured using S-LANSS at baseline without follow up
7. The Central Sensitisation Inventory (CSI) is a to identify patients who have symptoms that may be related to central sensitization (CS) or central sensitivity syndromes (CSS) at baseline without follow up
8. Pain assessed by Visual analog scale (VAS) at baseline without follow up
9. Quality of life with Short Form-36 (SF-36) at baseline without follow up
10. The functionality of the lower limps measured with Lower Extremity Functional Scale (LEFS) at baseline without follow up
11. The symptoms of the patients will be assessed from the neurodynamics tests (Slump, SLR, Femoral slump test) at baseline without follow up
12. Muscle strength from neurological examination at baseline without follow up
13. Reflexes from neurological examination at baseline without follow up
14. Quantitative sensory testing (hot, cold, vibration, pinprick, light touch, discrimination points) at baseline without follow up

Overall study start date
22/01/2019

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Patients with sciatica diagnosed by spine specialist in a private or public hospital and referred to physiotherapy
2. Pain in the lumbar region that reflects at the lower extremity in either a dermatomal distribution or not
3. Subjective neurological symptoms in one lower extremity, such as numbness, tingling, burning, weight sensation and crippling pain
4. Aged 18-75 years old
5. Ablity to read and communicate in Greek
6. Willingness to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Suspected serious spinal pathology or clinical red-flags such as cauda equina syndrome, suspicion of spinal tumours, infection, fractures and inflammatory spondyloarthropathy
2. Previous lumbar spine surgery
3. Previous lower extremity surgery
4. Currently receiving ongoing care from or have been in consultation with a secondary care doctor or physiotherapist for the same problem in the last 3 months
5. Serious co-morbidity preventing them from attending the research clinic and/or undergoing assessment and interventions
6. Severe enduring mental health condition
7. Pregnancy
8. Current participation in any other research study because of symptoms of back and leg pain or sciatica

9. Scoliosis of the spine >10 degrees, as measured on an X-ray
10. Taking steroid medications to treat neurological symptoms during the research period

Date of first enrolment
30/06/2020

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
Greece

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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
University of West Attica

Results and Publications

Publication and dissemination plan
A study protocol is not currently available online. At the end of data analysis, the results of the study will be published in international congress and electronic scientific journals.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Nikolaos Kontakiotis (kontak766@hotmail.com). Type of data: row data of primary and secondary outcome measures. Availability: from 01/12/2021. Access criteria: systematic reviews, quantitative synthesis for studies in the same scope of interest, peer review reasons. Consent from participants is obtained according to GDPR data protection.

IPD sharing plan summary
Available on request