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Hybrid single-photon emission computed tomographycomputed tomography (SPECT-CT) imaging results in chronic low back pain patients as compared to an asymptomatic control group

Submission date
26/12/2013

Recruitment status
No longer recruiting

Registration date
17/02/2014

Overall study status
Completed

Last Edited
16/01/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
For patients with low chronic low back pain that is not cured by conservative treatment, more invasive treatments can be considered. Those treatments may consist in injection, application of high frequency current or surgery. Success is dependent on how precisely the painful structure is identified. The new molecular imaging modality SPECT-CT detects increased bone metabolism during the degeneration process. It might be helpful in identifying the chronic low back pain phenotype. We want to evaluate the sensitivity of this molecular imaging modality in a group of patients suffering from chronic low back pain, as compared to a control group with no chronic back pain.

Who can participate?
Patients older than 18 years with chronic (> 3 months) low back pain without a specific pain phenotype on MRI, CT and classical X-Ray are referred for SPECT-CT imaging. In the control group, the patients were referred for SPECT-CT for other reasons than chronic low back pain.

What does the study involve?
Patients are asked if they consent to the analysis of their data. All patients undergo a SPECT-CT as planned within the diagnostic process for their condition.

What are the possible benefits and risks of participating?
This study is about data analysis only and there are no benefits or additional risks in participating. On rare occasions patients may be allergic to the product that is injected for imaging.

Where is the study run from?
AZ Nikolaas Hospital, Sint Niklaas, Belgium.

When is the study starting and how long is it expected to run for?
August 2013 to January 2014.

Who is funding the study
The SPECT-CT is part of the normal diagnostic process and is paid for by the standard procedure (health insurance). Costs for data recording and analysis are covered by the investigator.

Who is the main contact?
Dr Erik Van de Kelft, Director of the Neurosurgery Department, erik.vandekelft@aznikolaas.be
Dr Koen Melis, Director of the Neuroradiology Department, koen.melis@aznikolaas.be

Contact information

Type(s)
Scientific

Contact name
Dr Erik Van de Kelft

Contact details
Moerlandstraat, 1
Sint Niklaas
Belgium
9100
+32 (0)3 760 21 72
erik.vandekelft@aznikolaas.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2013-06/02

Study information

Scientific Title
Evaluation of the prevalence of increased Phosphorus uptake at lumbar level during SPECT-CT in a group of patients with low back pain as compared to an asymptomatic a control group

Study objectives
SPECT-CT shows hotspots at places with an increased phosphate metabolism due to mechanical stress. This is indicative for increased bone metabolism as result of the degeneration process. We hypothesize that the prevalence of hotspots observed during SPECT-CT will be higher in the group of patients with chronic low back pain as compared to an asymptomatic control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of AZ Nikolaas, Sint Niklaas Belgium, Ref: EC 13022

Study design
Prospective comparative study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Sensitivity of SPECT-CT in the identification of the pain phenotype when analyzing chronic low back pain

Interventions
Patients with chronic low back pain (more than 3 months) are referred for SPECT-CT imaging. In the control group, the patients were referred for SPECT-CT for other reasons than chronic low back pain.

All patients undergo a SPECT-CT as planned within the diagnostic process for their condition. The imaging data will be analyzed.

Intervention Type
Procedure/Surgery

Primary outcome measure
Number of patients with hotspots on SPECT-CT in the group with chronic low back pain, compared to the number of patients with hotspots on SPECT-CT in the group without chronic low back pain.

Secondary outcome measures
Analysis of the structures that show activity in both groups. The SPECT-CT images are read by the neuroradiologist immediately after the investigation. As the value of SPECT-CT as diagnostic tool for spinal pain is measured the interpretation of the images is done only once.

Overall study start date

08/08/2013

Completion date
30/01/2014

Eligibility

Key inclusion criteria
1. Patients older than 18 years
2. Referred to the department of medical imaging for SPECT-CT
3. Having signed the informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
200

Key exclusion criteria
1. Recent vertebral fractures
2. History of lumbar spine surgery
3. Diagnosed malignancy
4. Pregnancy
5. Contraindication for injection 99mTc hydroxymethane diphosphonate (99MTc-HDP)

Date of first enrolment
08/08/2013

Date of final enrolment
30/01/2014

Locations

Countries of recruitment
Belgium

Study participating centre
Moerlandstraat, 1
Sint Niklaas
Belgium
9100

Sponsor information

Organisation
AZ Nikolaas

Sponsor details
c/o Van de Kelft Erik
AZ Nikolaas
Moerlandstraat 1
Sint Niklaas
Belgium
9100
+32 (0)3 760 21 72
erik.vandekelft@aznikolaas.be

Sponsor type
Hospital/treatment centre

Website
http://www.neuro-chirurgie.org/BENL/site/index.aspx

Funder(s)

Funder type
Industry

Funder Name
Neuro-surgery.org (Belgium)

Funder Name
The investigation (SPECT-CT) is part of the normal diagnostic process for the patients, thus the costs involved are carried by the patients individual health insurance.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017	16/01/2020	Yes	No