ISRCTN43417727 https://doi.org/10.1186/ISRCTN43417727

Inter-examiner reliability of diagnostic criteria

Submission date
09/07/2013

Recruitment status
No longer recruiting

Registration date
18/07/2013

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Different types of low back pain (e.g. sacroiliac, discogenic and facet joint pain) have been identified. Treatment has become more effective due to the availability of specific treatments. Several diagnostic tests have been developed, but little is known about whether different doctors use the same diagnostic tests. This study aims to find out the inter-examiner reliability of the different clinical tests used to diagnose patients.

Who can participate?
Patients aged 18 or over with signs and symptoms of low back pain.

What does the study involve?
A physical examination of patients is done independently by two experienced pain specialists and one experienced surgeon. The list of tests prescribed by the three doctors are then compared and the tests are judged based on their presence in the list.

What are the possible benefits and risks of participating?
Improving diagnostic tests for identifying subtypes of low back pain increases the possibility for better treatment. We expect that this will improve overall success in treatment. No major risks are involved in this study.

Where is the study run from?
This study is run from Lievensberg Hospital, Bergen op Zoom, The Netherlands.

When is the study starting and how long is it expected to run for?
The study started in January 2013 and is expected to run for two years.

Who is funding the study?
This study is funded by the Centre for Pain Medicine, Erasmus University MC, Rotterdam, The Netherlands.

Who is the main contact?
C.W.J. van Tilburg, MD, FIPP
vtilburg@ziggo.nl

Contact information

Type(s)
Scientific

Contact name
Dr Cornelis Wilhelmus Jacobus van Tilburg

Contact details
Multidisciplinary pain centre
Lievensberg hospital
Boerhaaveplein 1
Bergen op Zoom
Netherlands
4624 VT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL36822.078.11

Study information

Scientific Title
Inter-examiner reliability of diagnostic criteria for diagnosing sacroiliac joint - discogenic and facet joint pain

Study objectives
Investigate the inter-examiner reliability of diagnostic tests in diagnosing sacroiliac joint - discogenic and facet joint pain. Our study aims to assess the reliability between examiners (pain specialists and orthopedic surgeons are involved) of the clinical tests used to select the patients in these studies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval has been granted by the Medical Ethics Committee (Medisch Ethische Toetsings Commissie) (METC) Erasmus MC, Rotterdam, The Netherlands on 14th November, 2012, reference number MEC-2011-246.

Study design
Observational 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
Chronic low back pain

Interventions
Patients will receive three separate consultations from two anaesthesiologist-pain specialists and one orthopaedic surgeon, during which every item from the list with diagnostic criteria are judged on their presence or absence.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The results of the diagnostic tests by two pain specialists and one orthopaedic surgeon.

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/01/2013

Completion date
10/01/2015

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Chronic low back pain lasting for more than 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Total final enrolment
100

Key exclusion criteria
Presence of red flags as possible fracture, tumor or infection

Date of first enrolment
10/01/2013

Date of final enrolment
10/01/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Multidisciplinary pain centre
Bergen op Zoom
Netherlands
4624 VT

Sponsor information

Organisation
Erasmus University Medical Centre (MC) (Netherlands)

Sponsor details
c/o Frank Huygen
Centre for Pain Medicine
's-Gravendijkwal 230

Rotterdam
Netherlands
3015 CE

Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
University/education

Funder Name
Centre for Pain Medicine, Erasmus University MC, Rotterdam, Netherlands.

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	28/05/2018	29/05/2020	Yes	No