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The role of provocative discography in surgical treatment for patients with chronic low back pain

Submission date
27/06/2010

Recruitment status
No longer recruiting

Registration date
31/01/2012

Overall study status
Completed

Last Edited
14/02/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Lumbar back pain is extremely common, but usually gets better over time. Nevertheless, some people become seriously debilitated. It is important to find the specific pain generator responsible for these symptoms. A provocative discogram is a diagnostic test to help identify which of the disc(s) of the spine, if any, are causing pain. The aim of this study is to compare the surgical outcomes of patients operated on with or without discography before the operation.

Who can participate?
Patients aged 23 - 74 with chronic (long-term) low back pain

What does the study involve?
Participants are randomly allocated into two groups. Participants in one group undergo provocative discography to find out the main generator of the pain, and those with positive findings are sent to undergo surgical treatment. Participants in the other group do not undergo provocative discography and all undergo surgery. The surgical outcomes of the two groups are compared.

What are the possible benefits and risks of participating?
All participants undergo standard tests and after that surgical treatment which will hopefully improve their health and physical function. Discography has proven to be a relatively safe procedure. Major risks of procedure include infection, hematoma (a solid swelling of clotted blood) and nerve injury. These complications are extremely rare. The most feared complication is discitis (inflammation between the discs) which is also extremely rare.

Where is the study run from?
University of Zagreb School of Medicine and the Clinic of Traumatology Zagreb (Croatia)

When is the study starting and how long is it expected to run for?
January 2003 to December 2009

Who is funding the study?
Ministry of Health (Croatia)

Who is the main contact?
Petra Margetic
hpetra23@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Marin Stancic

Contact details
Clinic for Neurosurgery
KBC Zagreb
Kispaticeva 12
Zagreb
Croatia
10000
-
marin@stancic.eu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The role of provocative discography in surgical treatment for patients with chronic low back pain: a randomised controlled study

Study objectives
Provocative discography is able to locate the precise disc of clinical significance and determine the exact cause of the pain

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Medical Ethics Committee of Clinic for Traumatology Zagreb, 28/11/2007
2. Medical Ethics Committee of Zagreb Medical University, 04/02/2008

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Low back pain/ischiatic pain

Interventions
At first all 310 patients were randomized into a trial group with 207 patients and a control group with 103 patients.

Patients in trial group filled in the Oswestry, Zung and MSPQ test, if the results did not show high depression values (Zung results more than 33) and somatisation (MSPQ results more than 12 in patients with Zung results between 18 and 33) we considered the patients adequate to be sent to provocative discography.

Patients with positive findings on provocative discography were sent to surgical treatment. Surgery was performed on patients in trial group with positive finding on discography and also on all patients in control group without discography.

All patients, in both groups were categorized by Thalgott. In cases categorized as C and/or D changes on more segments (mostly two) we performed transpedicular fixation. In cases categorized E and F group by Thalgott we performed circumferential posterolateral and intercorporal fixation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Statistically significant difference between two pre-operative groups should be 4 points or 8%
2. Statistically significant difference between pre-operative and post-operative groups should be 10 points or 20%

Secondary outcome measures
1. 36-item Short Form Health Survey (SF-36) update
2. Likert bipolar scaling method measuring either positive or negative response to a statement

Overall study start date
01/01/2003

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Aged 23 - 74 years, either sex
2. Chronic low back pain and ischiatic pain
3. Radiological findings describe more than one cause of the pain
4. Uncertain clinical status after complete diagnostic imaging

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
310 patients

Key exclusion criteria
1. Tumour
2. Trauma
3. Psychiatric disease
4. Pregnancy

Date of first enrolment
01/01/2003

Date of final enrolment
31/12/2009

Locations

Countries of recruitment

Croatia

Study participating centre
KBC Zagreb
Zagreb
Croatia
10000

Sponsor information

Organisation
KBC Zagreb [Klinički bolnički centar Zagreb] (Croatia)

Sponsor details
c/o Marin Stancic
Clinic for Neurosurgery
Kispaticeva 12
Zagreb
Croatia
10000

Sponsor type
Hospital/treatment centre

Website
http://www.kbc-zagreb.hr/

ROR
https://ror.org/00r9vb833

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
KBC Zagreb [Klinički bolnički centar Zagreb] (Croatia)

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