

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	<input type="checkbox"/> Prospectively registered
Registration date 31/01/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/02/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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%

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/00r9vb833>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

KBC Zagreb [Klinički bolnički centar Zagreb] (Croatia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration