BEHANDELING VAN CHRONISCHE DISCOGENE LAGE RUGPIJN MET METHYLEEN BLAUW.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26862

Source
NTR

Brief title
IMBI

Health condition

axial lumbar low back pain discus discogenic intradiscal lage rug pijn lumbaal tussenwervelschijf

Sponsors and support

Primary sponsor: MUMC-Maastricht University Medical CentreDepartment of Anesthesiology and pain managementPO Box 58006202 AZ MaastrichtThe Netherlands. Addition 8-10-2013: Financed by ZonMW. The study is carried out in 2 additional centra.
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. Mean pain NRS; (Numeric rating scale) measured three times a day for 4 days;

2. Patients global perceived Effect (7point Likert scale);

3. Primary endpoint at 6 months.

Secondary outcome

1. Used analgesics;

2. Oswestry Disability Index;

3. Rand-36;

4. EuroQol;

5. Working status;

6. MPQ-DLV.

Study description

Background summary

N/A

Study objective

Intradiscal Methylene blue injection(IMBI) treatment reduces the pain and improves the patients global perceived effect (PGPE) in patients suffering from chronic axial low back pain from discogenic origin and to prove that IMBI treatment is safe and causes little side effects.

Study design

6, 12, 26, 52 and 104 weeks.

Intervention

The first 15 patients are included in a prospective case series without randomization (pilot study). If in this pilot study MB proves to be effective and a RCT feasible, a RCT will start. Al patients with discogenic LBP follow a standardized treatment schedule. The conservative treatment consists of medication according the scheme of the World health organisation (WHO):

1. Step 1 (Paracetamol and eventually NSAID’s);

2. Step 2: Non-opioid medication: Tramadol.

Patients receive discography when there is no treatment effect. If a discography is positive the patient is included and, in case of the RCT, randomised into the MB or the placebo group.

After proper patient selection and informed consent patients are scheduled for this methylene blue (MB) study. All patients are to be intradiscally injected with 1 ml of methylene (10mg/ml) blue followed by injection of 1 ml 2% Lidocaine hydrochloride.

Randomized clinical trial:

1. MB group: 1 ml of methylene (10mg/ml) blue followed by injection of 1 ml 2% Lidocaine hydrochloride;

2. (RCT) Placebo group: 1 ml of isotonic saline , followed by injection of 1 ml 2% Lidocaine hydrochloride.

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Eligibility criteria

Inclusion criteria

1. Axial low back pain of presumed discogenic origin of at least 6 months duration and non responsive to treatment of at least 6 months conservative medical management;

2. History consistent with discogenic low back pain (e.g. predominant axial pain produced on lumbar motion, significant functional limitation in sitting duration and tolerance);

3. A neurological exam without marked motor deficit;

4. Age between 18 and 65 years;

5. Pain intensity should be NRS 5 or higher;

6. In provocative discography Modified Dallas Criteria 1-4
7. A provoked pain of at least 7 (NRS) or 70% of maximum pain.

Exclusion criteria

1. Severe disc degeneration at the affected level as evidenced by >50% disc height loss on plain anteroposterior and lateral lumbar radiographs or CT/MRI;

2. Extruded or sequestered herniated nucleus pulposus at the affected level(s);

3. Body Mass Index BMI of ≥ 35;

4. Weighted pain with NRS below 5;

5. Previous lumbar back surgery (e.g. Laminectomy, discectomy or fusion);

6. Invasive intradiscal procedure previously performed at the same level;

7. Moderate to severe spinal stenosis due to osteophyte and/or ligamentous overgrowth as evidenced by MRI or CT, provided stenosis is the cause of pain;

8. Moderate to severe endplate degenerative changes at the affected levels;

9. Grade 1-2 spondylolisthesis;

10. Pregnancy;

11. Coagulopathy or oral anti-coagulant therapy;

12. Infection;

13. Patients incapable of following verbal or written instructions or with psychiatric problems potentially interfering with cooperation in the study;

14. Discography:

A. That shows a posterior annular disruption to extend into the outer annulus or beyond the confines of the outer annulus;

B. Discography without pain reproduction at the affected level(s), or with discordant pain at adjacent unaffected levels at up to 50 Psi above opening pressure;

C. Pain provocation in disc at pressures >50 Psi above opening pressure;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	63
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-09-2010

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2438
NTR-old	NTR2547
Other	METC MUMC / EudraCT : 2010-09 / 2010-022025-15 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A