The efficacy of the IDD-protocol with Accu-Spina for patients with low back pain

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The primary objective of the study is to investigate whether the IDD (Intervertebral Differential Dynamics) protocol with Accu-Spina on the VAS low back pain score at 3 months posttreatment.

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30194

Source
ToetsingOnline

Brief title
Accu-Spina

Condition

- Joint disorders
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
backpain, Low-Back Pain

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Materiele ondersteuning van Producent Accu-Spina apparaat,Steadfast Corporation Limited

Intervention

Keyword: Conservative, Intervertebral disc, Low-Back Pain, Traction

Outcome measures

Primary outcome

· VAS score for low back pain

Secondary outcome

· VAS score for leg pain

· VAS score for satisfaction

· Oswestry disability index

· SF-36

Study description

Background summary

Low back pain poses a significant problem to society. An annual growth rate of 20% in costs is expected for the next five years in the US. Although initial conservative therapy may be beneficial, persisting chronic low back pain (LBP) may frequently lead to surgical intervention. Any non- invasive or minimal invasive treatment as an alternative to surgery deserves attention for the possible benefit to the LBP patient. The Accu-Spina System is an FDA cleared, class II medical device that delivers a non - invasive dynamic therapy focused on the treatment of the intervertebral disc when it is considered the main source of LBP. The mechanism of the device is unloading of the intervertebral disc and facet joint due to temporary repeated distraction, positioning and relaxation cycles. In a treatment program in which is opted for sequential treatment, this program may relieve LBP and create an environment for disc regeneration. The hypothesis behind the hypothesized working mechanism may be that a negative intradiscal pressure during distraction may increase nutrient flow into the disc.

Study objective

The primary objective of the study is to investigate whether the IDD (Intervertebral Differential Dynamics) protocol with Accu-Spina on the VAS low back pain score at 3 months posttreatment.

Study design

The study is a double blind, single center, randomised controlled trial of a non-invasive treatment in the early stage of introduction in the European Union. For the study, 60 consecutive patients will be included. These patients will be evaluated pretreatment and posttreatment at 2 and 6 weeks and at 3 months.

Intervention

The intervention under investigation is the Accu-Spina treatment. The therapeutic effect of the Accu-Spina treatment is accomplished through distraction to the affected motion segment. The distraction yields a negative pressure in the intervertebral disc facilitating influx of fluids, oxygen and nutrients. The Accu-Spina protocol consists of 20 treatments of half an hour over 6 weeks.

The intervention will be applied by one physiotherapist. The intervention will be accompanied by conservative graded activity for as well the experimental as control group. The graded activity program will start 2 weeks before initiation of treatment with the Accu-Spina protocol and will end at the same time. The graded activity program consists 4 days per week with each of 2 hours of training.

Study burden and risks

Burden for the patient is the time investment and treatment sessions at the Accu-Spina apparatus. The distraction sessions are not painfull and hardly to distinguish between the massage parts of the session, which are considered pleasant treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

· Low back pain for more than 3 months
· Bulging disc
· Lumbar degenerative disc disease
· Place of residence within 25 km from Nijmegen

Exclusion criteria

· Previous surgical treatment with dynamic stabilisation, fusion or disc replacement
· Radicular leg pain
· Malignancy
· Pregnancy
· Osteoporosis
· Refusal of the patient to participate (Dependend on requirement)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL13075.091.06