

# Efficacy of orthomanual treatment in addition to usual care in patients with low back pain in a painclinic population.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38387

### Source

ToetsingOnline

### Brief title

Efficacy of orthomanual treatment

### Condition

- Other condition

### Synonym

low back pain/ lumbago

### Health condition

standsafwijkingen van de wervelkolom

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Research is facilitated by the EMGO institute of the VU university; extra costs are paid for by the Dutch Association of Orthomaneal Doctors (NVOMG)

## Intervention

**Keyword:** Efficacy, low back pain, orthomaneal treatment, painclinic

## Outcome measures

### Primary outcome

Outcome measures after 3, 6, and 12 months

Pain: VAS

Backspecific function: Roland Morris Disability Questionnaire

5 scale general measure of change

### Secondary outcome

Outcome measures after 3, 6, and 12 months

Generic scale: Euroqol

Other treatments (out of protocol) and side effects will be recorded

## Study description

### Background summary

Orthomaneal medicine is a manipulative treatment that has been developed in the Netherlands. The technique is frequently used in the treatment of chronic low back pain. A large observational study was conducted which had a short follow-up period and which used only limited measurement instruments. In this study about 3/4 of the patients reported an improvement of their complaints. This result is compatible with the experience of orthomaneal physicians that the technique seems to be effective in the treatment of patients with long standing low back pain that has shown to be refractory to other types of

(manipulative) treatment.

## **Study objective**

In the proposed study we wish to investigate whether orthomaneual treatment is of additional value in the treatment of a population of patients with chronic low back pain. We aim to recruit a population that has been referred for evaluation to the painclinic, because these patients will generally have long standing complaints that have shown to be refractory to the usual first-line interventions.

## **Study design**

Randomized controlled trial

## **Intervention**

Intervention 1: usual care by painclinic

Intervention 2: usual care by painclinic + orthomaneual treatment

## **Study burden and risks**

Burden:

Next to the painclinic treatment patients in the interventiongroup will be referred to an orthomaneual physician. The first consultation will be scheduled within three weeks after inclusion. A normal medical history and a normal medical examination will be conducted, together with the orthomaneual examination, mainly to verify the possibility to treat the patient by orthomaneual techniques, and to reconfirm in- and exclusioncriteria. Generally a series of 5-7 treatments is needed for a first correction. After three months the patient should be re-examined and in many cases a few corrections have to be repeated. If the treatment has been effective patients are advised to consult their physician only when complaints return. If the treatment has been ineffective it is possible that further treatment is advised. Generally 8-10 sessions of approximately 20 min. are needed in the first year.

Risk:

There is some literature about possible adverse effects of manipulative treatment in general. It shows that minor side effects, like temporary dizziness, are common after manipulation of the cervical spine, but that serious side effects are extremely rare. Reported side effects most frequently result from rotatory HVT techniques that are not used in orthomaneual treatment. (safety reporting p. 8)

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

non specific low back pain  
duration at least 3 months  
able to answer questionnaires in Dutch  
no previous orthomaneual treatment

### Exclusion criteria

contraindications for manipulation  
specific low back pain  
condition influencing treatment or outcome

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2009
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	18-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-08-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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	NL22636.029.08