Effect of Infection, Modic and Inflammation on Clinical Outcomes in Radiculopathy 2

Published: 01-04-2021
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To explore the clinical role of infection and inflammation in lumbar and cervical radiculopathy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52609

Source
ToetsingOnline

Brief title
EIMICOR 2

Condition

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

Synonym
disc herniation, hernia, radicular syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: EANS & Neurochirurgie fonds

Intervention

Keyword: Disc herniation, Infection, inflammation, Radiculopathy

Outcome measures

Primary outcome

This study will explore the effects and interactions of bacterial infection, disc inflammation and Modic Changes on the clinical outcome of patients with cervical or lumbar disc herniation. To assess these effects, a mean difference over the course of one-year follow-up of 2-point difference on a 11 point NRS scale will be regarded as clinical relevant and thus used as main study parameter.

Secondary outcome

1. A secondary aim of this study is to assess whether patients that suffer from disc inflammation benefit more from anti-inflammatory drugs than those without inflammation.

2. Another secondary aim of this study is to further explore the inflammation process by characterizing different types of macrophages (M1 and M2) and B and T cells.

3. At last this study aims to associate the presence of bacterial infection to the presence and type of Modic Changes.

Study description

Background summary

Recent findings have suggested that a bacterial infection of the herniated disc aggravates pain symptoms. This bacterial infection is often associated with the

presence of Modic changes. Besides, evidence indicates that inflammation is also involved in resorption of herniated tissue as well as pain induction.

Study objective

To explore the clinical role of infection and inflammation in lumbar and cervical radiculopathy.

Study design

prospective-(longitudinal) observational cohort study

Study burden and risks

During this study, the only burden for subjects will be filling in clinical questionnaires, and the only risk involved will be inadequate data handling. Because all the clinical questionnaires won't take longer than one and a half hour in total for the entire study, and the participating hospitals work with Good Research Practice (GRP); both the study burden and risks associated with participation are regarded as negligible. Even though there is no direct gain for the participants, by participating in this study they may benefit from its results in the future.

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

Lumbar patients: - Age 18-75 - a unilateral lumbosacral radicular syndrome, with at least the following criteria: - Radicular incitement: radiating pain from (a part of the) dermatome L4, L5 and/or S1 (obligatory). o Radiculopathy: abovementioned pain + paresis (MRC grade > 3) of the myotome and/or dysesthesia in (a part of) the dermatome and/or lowered or no knee reflex or Achilles heel reflex (not obligatory). o Present for at least 8 weeks - MRI verified lumbosacral disc herniation that is corresponding to the side of the symptoms (obligatory) - Indication for surgery (obligatory) - Informed consent (obligatory), Cervical patients: - Age 18-75 - a unilateral cervical radicular syndrome, with at least the following criteria: o Radicular incitement: radiating pain from (a part of the) dermatome C45, C56, C67 and/or C7T1 (obligatory). o Radiculopathy: abovementioned pain + mild paresis (MRC grade > 3) (not obligatory). o Present for at least 8 weeks - MRI verified cervical disc herniation that is corresponding to the side of the symptoms (obligatory) - Indication for surgery (obligatory) - Informed consent (obligatory)

Exclusion criteria

Lumbar: - Previous lumbar spinal surgery or chemonucleolysis - Paresis of MRC < 4 - History of spinal inflammatory disease - Instability that requires surgical fixation - Active infection at the time of surgery - Usage of Anti-biotics in the past six months - Pregnancy - Inadequate knowledge of the Dutch language , Cervical: - Previous cervical spinal surgery - Paresis of MRC < 4 - Myelopathy as major complaint - History of spinal inflammatory disease - Instability that requires surgical fixation - Active infection at the time of surgery - Usage of Anti-biotics in the past six months - Epidural steroid injection in the past six months - Pregnancy - Inadequate knowledge of the Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-01-2022
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO

Date:	01-04-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-09-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL73413.058.20