Studying the effectivity of injecting platelet rich plasma in painful disci, a randomised controlled trial study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26177

Source
Nationaal Trial Register

Brief title
PRP in disci

Health condition

low back pain, injection, PRP, discogenic diseases
lage rugpijn, injectering, PRP, discogene pijn.

Sponsors and support

Primary sponsor: Stichting Rugpoli
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The primary outcome is improvement in pain and function following platelet rich plasma injection.

The outcome will be measured by means of Numeric pain scale, Short form health Survey (SF-36), Roland Morris disability questionnaire.

Secondary outcome

Secondary outcomes include observation for any untoward side-effects including increased pain, bleeding, infection and motor or sensory deficits.

Study description

Study objective

An injection of 1cc PRP, taken and processed directly from the patient, in a lumbal disc with or without anular tear, without modic, significantly improves pain and functionality.

Study design

Outcome will be measured post injection at 1 week, 4 weeks, 2 months, 6 months, 1 year.

Intervention

The intervention to be studied is the intradiscal delivery of Platelet Rich Plasma for proposed symptomatic improvement in pain and function related to treatment of annular tears at the appropriate disc level, as determined by discography.

Contacts

Public

[default]
The Netherlands

Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

The patients are aged between 18 en 65 jaar.

Pain persists for an extended period of time (ie >3 months]

pain is not responsive to conservative treatment (oral medicatin, rehabilitation).
Maintained intervertbral disc heigths of at least 50% and protrusion less than 5mm on MRI.

Positive result on the discografie in conformity with Isis Guidelines.

The exclusion criteria are not applicable.

Exclusion criteria

Modic

Patients unable, according to protocol, to stop taking anticoagulantia.

Pregnancy.

systemic infection or skin infectin over the puncture site

Allergy to contrast

Psychiatric conditions

Solid bonefusion that does not allow access to the disc
Severe intervertebral disc protrusions lager than 5mm, extrusions, or sequestered fragment

Severe spinal canal compromise at the disc levels to be investigated

Spondylolisthesis level 2 or higher.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	96
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4004
NTR-old	NTR4176
Other	: Rugpoli
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A