PRP injections in disci

Published: 26-03-2014
Last updated: 23-04-2024

Researching if the injection of PRP with patients suffering from discogenic low back problems with or without anular tear, without modic has significant beneficial effects on pain and functionality.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44855

Source
ToetsingOnline

Brief title
PRP in disci

Condition

- Other condition

Synonym
discus degeneration, low back pain

Health condition

discogene lage rugklachten

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Rugpoli
Source(s) of monetary or material Support: uit budget van eigen instelling

Intervention

Keyword: disci, injection, PRP

Outcome measures

Primary outcome

The goal for the pilot study is a minimal clinically relevant improvement of

1,5 points NRS en 2 points RMDQ, after 2 months.

Based on the priliminary data from the USA the clinical expectance for the

patients who receive PRP is for pain from 7 to 5 points NRS in 12 months and

for functionality from 12 to 9 points RMDQ in 12 months. For patients in the

control group the expectance is half a point NRS 7 to 6.5 and RMDQ from 12 to

11.

Secondary outcome

none

Study description

Background summary

The prevelance of discogenic low back problems is high and in 66 percent of the patients,not treatable. Data from recent scientific research in the USA suggests that there is a possible solution for these patients. The researched intervention is injecting platelet rich plasma (PRP) in lumbar disci with an intradiscal injection. The prilimary results from the USA show a significant positive effect on pain and functionality.

Study objective

Researching if the injection of PRP with patients suffering from discogenic low back problems with or without anular tear, without modic has significant

beneficial effects on pain and functionality.

Study design

We start with a feasability pilot study including 10 patients. After analyzing and adapting the protocol we can start the RCT if the minimal results are reached.

Double blind randomised controlled trial. The tested hypothesis is:

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

The questionnaires used are the NRS (pain), Roland Morris (functionality) and the SF-36 (self reported health). Patients have to fill out the questionnaires 7 times; before the injection (baseline), 1 and 4 weeks after the injection (control of injection), and 2, 4, 6, and 12 months after the injection (data gathering).

Study burden and risks

The risks of participating are very low, there is a small risk of infection, bleeding and nerve damage because of the injection given in de disc. The burden of participating is one checkup appointment (telephone/visit) and filling out the questionnaires 7 times.

Contacts

Public
Selecteer

De Eiken 3
Delden 7491 HP
NL
Scientific
Selecteer

De Eiken 3
Delden 7491 HP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

discogenic low back problems
o Aged between 18-65
o Pain exists for a minimum period of 3 months VAS score min. 5.
o Pain does not respond to conservative treatment.
o Remaining discushight 50% minimum controlled by MRI- of CT scan.
o Extrusions of discus are 5 mm or less controlled by MRI- of CT scan.
o Positive result on discografie in conformity with Isis Guidelines. [46]

Exclusion criteria

o Modicse changes
o pregnancy
o Use of anticoagulantia
o skin at the puncturespot.
o Contrastallergy.
o Psychiatric disorder
o Solid bonefusion
o Severe spinal stenoses at the treatment level.
o Extrusions larger than 5mm
o Spondylolisthesis level 2 or larger.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-07-2014
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	08-05-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-02-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	13-07-2017

Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL46021.044.13