

Intervertebral disc regeneration using platelet-rich plasma

Submission date 14/05/2015	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 23/05/2015	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 22/05/2015	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Degenerative disc disease (DDD) is a common condition of the spine that can cause short or long term back pain. DDD frequently affects the lower back, and is a major cause of low back pain. The spine is made up of a column of bones (vertebrae), and between each vertebra there is a gel-filled disc. These discs cushion the vertebrae and act as 'shock absorbers', preventing the vertebrae from rubbing together. They also give the spine a degree of mobility. As people age, their discs become smaller and less flexible, which decreases the disc's ability to cushion the spine. Also, over time many people accumulate small 'wear and tear' injuries to their discs; unfortunately, discs are unable to heal themselves, so small injuries can become much worse over time. Despite DDD being very common, an effective treatment has not yet been established; many treatment strategies are aimed at managing the symptoms of DDD. A new treatment has recently been developed called platelet-rich plasma (PRP) therapy, which shows great promise in treating conditions such as knee and hip arthritis. In PRP therapy, blood is taken from the patient and then processed in a laboratory to separate the PRP component of it. PRP contains a concentration of various growth factors which are known to stimulate healing and tissue repair. The PRP portion is then re-injected into the patient at the site of injury. The aim of this small preliminary study is to see how effective and safe PRP therapy is when used to treat DDD.

Who can participate?

Adults diagnosed with DDD or experiencing chronic lower back pain for more than 3 months.

What does the study involve?

All participants are given a PRP injection into their affected spinal discs. Participants are asked to complete questionnaires and perform physical assessments before treatment, then again at 4, 8, 16, 24, 32, 40 and 48 weeks following treatment.

What are the possible benefits and risks of participating?

Participants will benefit from receiving PRP therapy at no cost. Potential risks of participation include the possibility of neurological deterioration or discitis in the treated discs.

Where is the study run from?
Mie University Hospital (Japan)

When is the study starting and how long is it expected to run for?
April 2009 to May 2012

Who is funding the study?
Ministry of Education, Culture, Sports, Science and Technology (Japan)

Who is the main contact?
Dr K Akeda

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Regenerative therapy of intervertebral disc using platelet-rich plasma growth factors

Study objectives
Platelet-rich plasma (PRP) has the potential to repair degenerated intervertebral discs. Intradiscal injection of PRP for the treatment of low back pain patients with degenerated intervertebral discs would be a safe and effective treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of Mie University Hospital, 04/07/2008, ref: 936.

Study design

Phase I prospective feasibility study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Degenerative disc disease

Interventions

One intradiscal injection of autologous platelet-rich plasma.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Efficacy assessment: pain-related efficacy of this treatment will be assessed at baseline, and at 4, 8, 16, 24, 32, 40, 48 weeks following treatment:

1. Visual analog scale (VAS) for back pain
2. Roland-Morris Disability Questionnaire (RDQ) for back pain-related disability
3. Neurological assessments (motor strength, sensory function and reflexes)

Safety assessment: the safety of this treatment will be evaluated in terms of neurological changes. Radiological examination includes:

1. Changes in disc height, lumbar lordosis angle, MRI morphology and T2-value.
2. The presence or absence of adverse events will also be evaluated through the follow-up period.

Key secondary outcome(s)

VAS pain score.

Completion date

01/05/2012

Eligibility

Key inclusion criteria

1. Aged >18
2. Chronic low back pain without leg pain for more than 3 months
3. One or more lumbar discs (L3/L4 to L5/S1) with evidence of degenerative changes on magnetic resonance imaging (MRI) maintenance of 50% or more of normal disc height
4. At least one symptomatic disc confirmed using standardised provocative discography and/or disc block

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Abnormal neurological symptoms (e.g. radiculopathy) with lumbar spinal stenosis or spondylolisthesis
2. Inflammatory arthritis (e.g. discitis)

Date of first enrolment

01/05/2008

Date of final enrolment

01/12/2011

Locations**Countries of recruitment**

Japan

Study participating centre

Mie University Hospital

1577 Kurimamachiya-cho

Tsu

Japan

514-8507

Sponsor information**Organisation**

Mie University Graduate School of Medicine

ROR

<https://ror.org/01529vy56>

Funder(s)

Funder type

Government

Funder Name

Ministry of Education, Culture, Sports, Science and Technology (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request