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Intervertebral disc regeneration using platelet-rich plasma

Submission date
14/05/2015

Recruitment status
No longer recruiting

Registration date
23/05/2015

Overall study status
Completed

Last Edited
22/05/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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.

Secondary outcome measures
VAS pain score.

Overall study start date
01/04/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
More than ten participants

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
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514-8507

Sponsor information

Organisation
Mie University Graduate School of Medicine

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Sponsor type
University/education

ROR
https://ror.org/01529vy56

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Preliminary results will be submitted mid-2015.

Intention to publish date
01/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request