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Comparing platelet-rich plasma extracted from a patient's own blood with corticosteroid injections in the treatment of carpal tunnel syndrome

Submission date
13/03/2020

Recruitment status
No longer recruiting

Registration date
20/03/2020

Overall study status
Completed

Last Edited
20/08/2021

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Carpal tunnel syndrome (CTS) is when there is pressure on a nerve in the wrist that causes tingling, pain and numbness in the hand and fingers. Steroid injections can be used to reduce inflammation and pressure around the nerve, but these often have to be repeated. CTS can also be treated with surgery.
Platelet-rich plasma (PRP) is made from a person's blood by taking out the white and red blood cells by centrifugation (spinning very fast in a tube), leaving a liquid rich in platelets, which are cell fragments involved in blood clotting, and substances involved in healing processes.
PRP injections are thought to speed up healing of sports injuries and conditions involving nerve damage. Some studies have shown that PRP injection can speed up resolution of CTS. This study aims to compare injection of PRP prepared in two different ways with steroid injections in patients with mild to moderate CTS.

Who can participate?
Adults aged 18-65 years who are otherwise healthy with mild to moderate CTS in one wrist only.

What does the study involve?
Participants were randomly allocated to one of three groups. One group received a single injection of a steroid drug into the wrist. The other two groups had blood taken. For one of these groups, PRP was prepared using a single centrifugation step and for the other group, PRP was prepared using two centrifugation steps. Both groups received a single injection of PRP into the affected wrist.
Before treatment and at 6 weeks and 3 months after treatment, all patients had tests of electrical function of the nerves in the wrist and were asked about their pain and CTS symptoms.

What are the possible benefits and risks of participating?
Steroid injections are a safe and established treatment for CTS. PRP is made from a person's own blood so there is no risk of infection or allergy. The injections and blood-taking might cause pain or discomfort.

Where is the study run from?
Zagazig University (Egypt)

When is the study starting and how long is it expected to run for?
July 2018 to September 2019

Who is funding the study?
The investigators are funding the study costs.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A prospective randomized controlled study to compare platelet-rich plasma with corticosteroid injection therapies in patients with carpal tunnel syndrome

Study objectives
PRP has better outcome in the treatment of CTS than steroid injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/12/2018, Zagazig University Institutional Review Board (Faculty of Medicine, Zagazig University, 44519 Ismailia - El-Zakazik Rd, Shaibet an Nakareyah, Zagazig 2, Ash Sharqia Governorate, Egypt; +201281229290; IRB_123@medicine.zu.edu.eg), ref: ZU-IRB#5014

Study design
Prospective randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Carpal tunnel syndrome

Interventions
The patients were randomly categorized a in 1:1:1 ratio into three groups PRP (i) group, PRP (ii) group and a third group (CS) that received local corticosteroid injection. Randomization was done by an independent researcher via computer generated randomization of study numbers on Excel® 2007 (Microsoft Co., Redmond, WA, USA). The clinical examination and nerve conduction study were done by a researcher who was blind to the type of the given injection.
Three peripheral venous blood samples were collected aseptically from each subject from the PRP groups into tubes with sodium citrate as an anticoagulant (BD® vacutainer). Whole blood platelet counts were determined using the cell counter (Sysmex Kx-21, Japan). In order to prepare PRP, the laboratory bench-top centrifuge (NÜVE: NF 400) was used at two different centrifugation times and rotation per minutes (rpm). PRP (i) was separated by a single centrifugation step at 1600 rpm for 8 min, and then the plasma above the erythrocyte layer was collected immediately. PRP (ii) was separated by two steps of centrifugation procedures. The samples were centrifuged first at 1200 rpm for 10 min; the plasma was separated from packed red blood cells and re-centrifuged at 3700 rpm for 10 min. The upper two-third volume of plasma, which is poor in platelets, was removed; the platelet pellet was suspended in a minimum quantity of plasma by gently shaking the tube and the PRP was activated endogenously the soft tissue collagen. The remnant PRP was counted using the cell counter (Sysmex Kx-21, Japan). The mean of platelet counts after each method was calculated and the enrichment percentage was determined as follows: Platelet enrichment = (platelet count PRP - platelet count whole blood) /platelet count whole blood × 100.
The hand of the patient was supinated in a neutral or slightly extended position for better exposure of the carpal tunnel. Lidocaine (1%; 0.5 ml) was injected using a 25-gauge needle at the distal wrist crease on the ulnar side to palmaris longus tendon (which can be located by having

the patient pinch the thumb and fifth fingers together while slightly flexing the wrist) and the needle was inserted nearly to ulnar at the midline. The needle was angled downward at 45 degrees toward the tip of the middle finger and advanced 1-2 cm as it traverses the flexor retinaculum. With the needle at the previous site, the syringe was changed and 1 ml of the prepared PRP (i) and (ii) was injected in the first and second group, respectively.
Using the same procedure, a single injection of methylprednisolone acetate of 1 ml at 40mg/ml was injected in the third group. Patients were observed for 30 min after injection and were advised to rest the injected arm for 48 h.

The researchers collected the following data:
1. Complete history from patient
2. Complete general and neurological examination
3. Electrophysiological diagnosis
4. Pain assessment by visual analog scale (VAS) repeated twice for all patients at 1.5 and at 3 months after injection
5. Boston CTS Questionnaire repeated twice for all patients at 1.5 and at 3 months after injection
6. Laboratory investigations including: complete blood counts, liver function tests, kidney function tests, blood sugar estimation, CRP and ESR
7. The PRP groups received one dose of PRP injection; while the third group received one dose of steroid injection

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Autologous platelet-rich plasma (PRP)

Primary outcome(s)
1. Pain assessed using a 1-10 visual analogue scale (VAS) reported by the patient at at 1.5 and 3 months after injection
2. Symptom severity assessed using the Boston Carpal Tunnel Syndrome Questionnaire (BCTSQ) at time of diagnosis and at 1.5 and 3 months after injection of treatment
3. Functional outcome assessed using the Boston Carpal Tunnel Syndrome Questionnaire (BCTSQ) at time of diagnosis and at 1.5 and 3 months after injection of treatment

BCTSQ evaluates two domains of CTS: (i) symptoms severity using a scale of 11 items (pain, paresthesia, numbness, weakness and nocturnal symptoms), and (ii) functional assessment using a scale of eight items (writing, buttoning, holding, gripping, bathing and dressing). The questionnaire is in a multiple choice format with scores ranging from 1 (mildest) to 5 (most severe). Each score was calculated as the mean of the response of the individual items.

Key secondary outcome(s))
Electrophysiological grading of CTS assessed using a nerve conduction velocity test at diagnosis and 1.5 and 3 months after injection of treatment

The electrophysiological study was conducted as per the American Association of Electrodiagnostic Medicine protocol by an expert neurologist. According to the neurophysiological grading for CTS, patients were classified as follows: very mild (grade 1), CTS

confirmed only with most sensitive tests (e.g., inching, combined sensory index, palm/wrist median/ulnar comparison); mild (grade 2), only orthodromic sensory nerve conduction velocity slow at <40 m/s with normal terminal motor latency; moderate (grade 3), motor terminal latency >4.5 ms and <6.5 ms with preserved sensory nerve action potential of the index finger.

Completion date
15/09/2019

Eligibility

Key inclusion criteria
1. Diagnosed with very mild to moderate unilateral CTS
2. Aged 18-65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Severe CTS
2. Bilateral CTS
3. Received non-steroidal anti-inflammatory drugs (NSAIDs) within 2 weeks of the study start
4. History of wrist surgery, polyneuropathy, cervical spondylosis, brachial plexopathy or thoracic outlet syndrome
5. History of thrombocytopenia or platelet dysfunction
6. Systemic infection
7. Renal or hepatic disease
8. Pregnancy
9. Previous steroid injection or surgical treatments for CTS
10. Psychiatric disorders or serious mental stress
11. Use of corticosteroid or anticlotting drugs

12. Diabetes mellitus
13. Uncontrolled hypothyroidism
14. Rheumatological disorders

Date of first enrolment
01/01/2019

Date of final enrolment
27/06/2019

Locations

Countries of recruitment
Egypt

Study participating centre
Zagazig university
Faculty of Medicine
Zagazig
Egypt
44519

Sponsor information

Organisation
Zagazig University

ROR
https://ror.org/053g6we49

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during this study will be included in the subsequent results publications.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/06/2020	20/08/2021	Yes	No