

Comparison of the outcome of Platelet-rich plasma and hyaluronic acid injections in the treatment of degenerative joint disease of knee

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#	Registration date
→ 1	2018-08-11, 1397/05/20

Protocol summary

Study aim	The aim of the present study is to compare the efficacy of platelet-rich plasma and hyaluronic acid injections in the treatment of knee osteoarthritis.
Design	The patients are assigned into three groups of at least 27 people. The assignment into the three groups of single PRP injection, double PRP injections and hyaluronic acid is conducted by random allocation.
Settings and conduct	This single-blinded controlled trial, in which the researcher is blinded, is performed on the patients aged 40-80 years old with osteoarthritis who are referred to Shahid Beheshti Hospital in Babol.
Participants/Inclusion and exclusion criteria	The inclusion criteria are as follows: Patients with diagnosis of bilateral knee osteoarthritis based on American college of Rheumatology, morning stiffness lasting less than 30 minutes, radiographic evidence of osteoarthritis, and symptoms lasting at least 3 months.
Intervention groups	Three groups: Single PRP injection, double PRP injections, hyaluronic acid
Main outcome variables	Primary objective: Change in Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) pain sub-scale.

General information

Acronym	
IRCT registration information	IRCT registration number: IRCT20180129038548N1 Registration date: 2018-08-11, 1397/05/20 Registration timing: registered_while_recruiting Last update: 2018-08-11, 1397/05/20 Update count: 0
Registration date	2018-08-11, 1397/05/20

Registrant information	<table><tbody><tr><td>Name</td><td>Seyed Mokhtar Esmailnezhad Ganji</td></tr><tr><td>Name of organization / entity</td><td></td></tr><tr><td>Country</td><td>Iran (Islamic Republic of)</td></tr><tr><td>Phone</td><td>+98 11 3219 9936</td></tr><tr><td>Email address</td><td>smsganjji@yahoo.com</td></tr></tbody></table>	Name	Seyed Mokhtar Esmailnezhad Ganji	Name of organization / entity		Country	Iran (Islamic Republic of)	Phone	+98 11 3219 9936	Email address	smsganjji@yahoo.com
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Scientific title	Comparison of the outcome of Platelet-rich plasma and hyaluronic acid injections in the treatment of degenerative joint disease of knee
Public title	Comparison of the Platelet-rich plasma and hyaluronic acid injections in treatment of knee osteoarthritis
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patients with diagnosis of bilateral knee osteoarthritis based on American college of Rheumatology. Morning stiffness lasting less than 30 minutes Radiographic evidence of osteoarthritis Symptoms lasting at least 3 months Exclusion criteria: Other knee joint diseases, like rheumatoid arthritis and gout. Intra-articular knee joint corticosteroid injection over the past two weeks
Age	From 40 years old to 80 years old
Gender	Both

Phase	3
Groups that have been masked	• Investigator
Sample size	Target sample size: 81
Randomization (investigator's opinion)	Randomized
Randomization description	The patients are randomly divided by using a computer-generated random number list. The subjects are assigned into different groups by random allocation. Allocation concealment is obtained by maintaining the randomization list by study statistician.
Blinding (investigator's opinion)	Single blinded
Blinding description	In this study, the researcher is blinded.
Placebo	Not used
Assignment	Parallel
Other design features	

Ethics committees

1													
Ethics committee	<table border="1"> <tr> <td>Name of ethics committee</td> <td>Ethics committee of Babol University of Medical Sciences</td> </tr> <tr> <td>Street address</td> <td>Ganjafrooz Street, Babol University of Medical Sciences</td> </tr> <tr> <td>City</td> <td>Babol</td> </tr> <tr> <td>Province</td> <td>Mazandaran</td> </tr> <tr> <td>Country</td> <td>Iran (Islamic Republic of)</td> </tr> <tr> <td>Postal code</td> <td>۴۷۱۷۶-۴۷۱۷۵</td> </tr> </table>	Name of ethics committee	Ethics committee of Babol University of Medical Sciences	Street address	Ganjafrooz Street, Babol University of Medical Sciences	City	Babol	Province	Mazandaran	Country	Iran (Islamic Republic of)	Postal code	۴۷۱۷۶-۴۷۱۷۵
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Approval date	2018-07-08, 1397/04/17												
Ethics committee reference number	IR.MUBABOL.HRI.REC.1397.082												

Health conditions studied

1	
Description of health condition studied	Osteoarthritis
ICD-10 code	M15.9
ICD-10 code description	Polyosteoarthritis, unspecified

Primary outcomes

1	
Description	Change in Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) pain sub-scale.
Timepoint	Weeks 4, 8 and 12 of treatment.
Method of measurement	Based on Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) and Visual Analogue Scale (VAS).

Secondary outcomes

1	
Description	Change in global Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC).
Timepoint	Weeks 4, 8 and 12 of treatment.
Method of measurement	Based on Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC).

Intervention groups

1	
Description	Intervention group: Single PRP Injection
Category	Treatment - Drugs

2	
Description	Intervention group: Double PRP Injection
Category	Treatment - Drugs

3	
Description	Control group: Hyalgan
Category	Treatment - Drugs

Recruitment centers

1																			
Recruitment center	<table><tbody><tr><td>Name of recruitment center</td><td>Shahid Beheshti Hospital</td></tr><tr><td>Full name of responsible person</td><td>Seyed Mokhtar Esmailnejad Ganji</td></tr><tr><td>Street address</td><td>Shahid Sargord Ghasemi Street, Shahid Beheshti Hospital</td></tr><tr><td>City</td><td>Babol</td></tr><tr><td>Province</td><td>Mazandaran</td></tr><tr><td>Country</td><td>Iran (Islamic Republic of)</td></tr><tr><td>Postal code</td><td>4716681451</td></tr><tr><td>Phone</td><td>+98 11 3225 2071</td></tr><tr><td>Email</td><td>beheshti@mubabol.ac.ir</td></tr></tbody></table>	Name of recruitment center	Shahid Beheshti Hospital	Full name of responsible person	Seyed Mokhtar Esmailnejad Ganji	Street address	Shahid Sargord Ghasemi Street, Shahid Beheshti Hospital	City	Babol	Province	Mazandaran	Country	Iran (Islamic Republic of)	Postal code	4716681451	Phone	+98 11 3225 2071	Email	beheshti@mubabol.ac.ir
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Sponsors / Funding sources

1	
Sponsor	<p>Name of organization / entity Vice Chancellor for Research and Technology of Babol University of Medical Sciences</p> <p>Full name of responsible person Dr. Reza Ghadimi</p> <p>Street address Ganjafrooz Street, Babol University of Medical Sciences</p> <p>City Babol</p> <p>Province Mazandaran</p> <p>Country Iran (Islamic Republic of)</p> <p>Postal code ۴۷۱۷۶-۴۷۱۷۶۵</p> <p>Phone +98 11 3219 9592</p> <p>Email info@mubabol.ac.ir</p>
Grant name	
Grant code / Reference number	
Is the source of funding the same sponsor organization/entity?	Yes
Title of funding source	Vice Chancellor for Research and Technology of Babol University of Medical Sciences
Proportion provided by this source	100
Public or private sector	Public
Domestic or foreign origin	Domestic
Category of foreign source of funding	<i>empty</i>
Country of origin	
Type of organization providing the funding	Academic

Person responsible for general inquiries

Contact	<p>Name of organization / entity Babol University of Medical Sciences</p> <p>Full name of responsible person Dr. Seyed Mokhtar Esmailnejad Ganji</p> <p>Position Associate professor</p> <p>Latest degree Specialist</p> <p>Other areas of specialty/work Orthopedics</p> <p>Street address Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran.</p> <p>City Babol</p> <p>Province Mazandaran</p> <p>Country Iran (Islamic Republic of)</p> <p>Postal code ۴۷۱۷۶-۴۷۱۷۶۵</p> <p>Phone +98 11 3219 9592</p> <p>Email smsnganji@yahoo.com</p>
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Person responsible for scientific inquiries

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Person responsible for updating data

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