Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison efficacy of triamcinolone and wrist splint in severe carpal tunnel syndrome in Pregnancy

Protocol summary

Summary

Objective: The main aim of this study is to compare the effectiveness of steroid injection and wrist splint in severe carpal tunnel syndrome (CTS) in pregnancy. Design: This study is a randomized clinical trial which will be accomplished from October 2012 to June 2013 at Shahid (S) Mofateh clinic on 70 pregnant women. The cases selected by blocked randomization among pregnant women who referred to obstetrics and gynecology clinic in Yasuj city in south- west of Iran. Setting and Conduct: Pregnant women that have symptoms (pain and paresthesia of fingers) and signs of CTS, such as positive Tinel and/or Phalen tests, refer to physiatrist for performing standard electrodiagnostic studies. Electrophysiologic parameters of median and ulnar nerves recorded before start of intervention. If there is severe CTS, the patients randomly classified in two groups. The first group receives 40 milligram(mg) triamcinolone acetonide (Triamhexal,40 mg/1 milliliter(ml), made by Holzkirchen factory ,Germany) intraarticular in carpal tunnel of involved wrist by physiatrist.The second group wears wrist splint that was product of Iran Odor Company for 8 weeks in nights . The patients evaluated by clinical and electrodiagnostic studies after 2 months from starting the intervention. In cases of observing changes from severe to lower stages of the disease in electrodiagnostic studies, treatment was considered successful and otherwise failed. Participants: Main inclusion criterion includes paresthesia of fingers that begin in pregnancy in ages between 15 and 49 years old y/o. Major exclusion criterion includes pre-pregnancy paresthesia of fingers and underlying disease such as diabetes mellitus. Intervention: The first group injected 40 mg of triamcinolone (intraarticular) in carpal tunnel of involved wrist. The second group received wrist splint that wear in nights for 8 weeks. Main outcome: Main outcomes includes detection of symptoms (pain and paresthesia of fingers) and severity of CTS in electrodiagnostic studies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110210799N3**
Registration date: **2013-02-12, 1391/11/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-12, 1391/11/24

Registrant information

Name
Parviz Yazdanpanah
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Yasuj University of Medical Sciences

Expected recruitment start date

2012-11-30, 1391/09/10

Expected recruitment end date

2013-05-30, 1392/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison efficacy of triamcinolone and wrist splint in severe carpal tunnel syndrome in Pregnancy

Public title
Efficacy of steroid injection and wrist splint in carpal tunnel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria includes women that had paresthesia of hands during pregnancy(pregnancy related carpal tunnel syndrome) and ages between 15 and 49 y/o). Exclusion criteria in this study are diabetes mellitus, collagen vascular disease, renal failure, hypothyroidism, rheumatoid disease, pre-pregnancy carpal tunnel syndrome, positive family history of neuropathy, carpal tunnel surgery and fracture of wrist bones.
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yasuj University of Medical Sciences
Street address
S.Motaheri street,Site of University
City
Yasuj
Postal code
7591741417
Approval date
2012-02-20, 1390/12/01
Ethics committee reference number
6/10/12/90/پ

Health conditions studied

1

Description of health condition studied
Carpal tunnel syndrome
ICD-10 code
G56
ICD-10 code description
Mononeuropathies of upper limb,Carpal tunnel syndrome

Primary outcomes

1

Description
Severity of pregnancy related CTS
Timepoint
In start of study and 2 months after intervention
Method of measurement
Clinical examination and electrodiagnostic studies

Secondary outcomes

1

Description
Pain and numbness of fingers
Timepoint
Before and 2 months after treatment intervention
Method of measurement
Visual analogue scale and electrodiagnostic studies

Intervention groups

1

Description
The second group wear wrist splint(product of Iran Odor company) for 8 weeks during nights.
Category
Treatment - Devices

2

Description
The first group receive 40 mg triamcinolone Acetonide(Triamhexal 40,1 mg crystalline suspension,intraarticular,manufactured of Holzkirchen factory in Germany)in involved wrist of severe CTS.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid(S).Mofateh Clinic of Yasuj
Full name of responsible person

Hossin Rahimipour

Street address

S.Jalil street,Medical College

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Yasuj University of Medical Sciences

Full name of responsible person

Doctor(Dr) Mohamad Akbartabar

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S.Motahari street,Site of University

City

Yasuj

Grant name

بودجه های پژوهشی دانشگاه

Grant code / Reference number

124013

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research,Yasuj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

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Position

Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Physiatrist

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty