Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Aug 2019

Comparative Study of Therapeutic Effects of Two Medical Intervention of Citalopram 4 Hours before Coitus and Each 12 Hours in Treatment Of Premature Ejaculation

Protocol summary

Summary
The purpose of this randomized clinical trial was to compare therapeutic effects of two medical interventions of citalopram, 4 hours before coitus and every 12 hours in the treatment of premature ejaculation. 113 men, aged 18-50 years old, with premature ejaculation were recruited and randomly assigned to receive citalopram, 20mg, 4 hours before coitus or every 12 hours for 8 weeks. Ejaculation time and adverse effects were measured and compared between groups.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201010304989N2
Registration date: 2010-12-12, 1389/09/21
Registration timing: registered_while_recruiting

Last update:
Update count: 0
Registration date
2010-12-12, 1389/09/21

Registrant information
Name
Bijan Rezakhaniha
Name of organization / entity
I.R.I Army University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2255 7435
Email address
bi_rezakhaniha@armyums.ac.ir

Recruitment status
Recruitment complete
Funding source
Personal funding

Expected recruitment start date
2009-04-04, 1388/01/15
Expected recruitment end date
2011-04-04, 1390/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Study of Therapeutic Effects of Two Medical Intervention of Citalopram 4 Hours before Coitus and Each 12 Hours in Treatment Of Premature Ejaculation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age between 18 and 50 years, documented history of primary premature ejaculation, sexual intercourse at least once a week Exclusion criteria: Drug noncompliance, past history of pelvic or central nervous system trauma or operation

Age
From 18 years old to 50 years old
Gender
Male

Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 113

Randomization (investigator's opinion)
Randomized
Randomization description

Blinding (investigator's opinion)
Not blinded
Blinding description

Placebo
Not used
### Ethics committees

<table>
<thead>
<tr>
<th>1</th>
<th>Ethics committee</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name of ethics committee</strong></td>
<td>I.R.I Army University of Medical Sciences</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td>I.R.I Army University of Medical Sciences, Etemad Zade Street, West Fatemi Street</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>Tehran</td>
</tr>
<tr>
<td><strong>Postal code</strong></td>
<td>1411718541</td>
</tr>
</tbody>
</table>

**Approval date**: 2009-02-19, 1387/12/01

**Ethics committee reference number**: 1531

### Health conditions studied

<table>
<thead>
<tr>
<th>1</th>
<th>Description of health condition studied</th>
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</thead>
<tbody>
<tr>
<td><strong>Preparation Ejaculation</strong></td>
<td></td>
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</table>

**ICD-10 code**: F52.4

**ICD-10 code description**: Premature Ejaculation

### Primary outcomes

<table>
<thead>
<tr>
<th>1</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Ejaculation time</strong></td>
<td></td>
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</table>

**Timepoint**: Before intervention, 4 weeks after intervention, 8 weeks after intervention

**Method of measurement**: with chronometer

### Secondary outcomes

<table>
<thead>
<tr>
<th>1</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Drug adverse effect</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Timepoint**: Before intervention, 4 weeks after intervention, 8 weeks after intervention

**Method of measurement**: Interview with patient

### Intervention groups

<table>
<thead>
<tr>
<th>1</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Citalopram, 20mg, orally, every 12 hours for 8 weeks</td>
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</table>

**Category**: Treatment - Drugs

<table>
<thead>
<tr>
<th>2</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Citalopram, 20mg, orally, 4 hours before coitus for 8 weeks</td>
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</tr>
</tbody>
</table>

**Category**: Treatment - Drugs

### Recruitment centers

<table>
<thead>
<tr>
<th>1</th>
<th>Recruitment center</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name of recruitment center</strong></td>
<td>Private clinic</td>
</tr>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Dr Bijan Rezakhaniha</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td></td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>Tehran</td>
</tr>
</tbody>
</table>

### Sponsors / Funding sources

<table>
<thead>
<tr>
<th>1</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name of organization / entity</strong></td>
<td>I.R.I Army University of Medical Sciences</td>
</tr>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>Dr Bijan Rezakhaniha</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td>I.R.I Army University of Medical Sciences. Etemad Zade Street, West Fatemi Street</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>Tehran</td>
</tr>
</tbody>
</table>

**Grant name**: |

**Grant code / Reference number**: |

**Is the source of funding the same sponsor organization/entity?**: Yes

**Title of funding source**: I.R.I Army 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**: empty

**Type of organization providing the funding**: empty
Person responsible for general inquiries

Contact
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Full name of responsible person
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Position
Urologist-Assistant Professor
Other areas of specialty/work
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Other areas of specialty/work
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Web page address

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