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
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I.R.I Army University of Medical Sciences
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Email address
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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

Public 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
Not blinded

Blinding (investigator's opinion)
Not used

Placebo
Not used
### Ethics committees

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Ethics committee</strong></td>
<td></td>
</tr>
<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>
<tr>
<td><strong>Approval date</strong></td>
<td>2009-02-19, 1387/12/01</td>
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<td><strong>Ethics committee reference number</strong></td>
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### Health conditions studied

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<tr>
<td><strong>Description of health condition studied</strong></td>
<td>Premature Ejaculation</td>
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<tr>
<td><strong>ICD-10 code</strong></td>
<td>F52.4</td>
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<td>Premature Ejaculation</td>
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### Primary outcomes

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<tr>
<td><strong>Description</strong></td>
<td>Ejaculation time</td>
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<tr>
<td><strong>Timepoint</strong></td>
<td>Before intervention, 4 weeks after intervention, 8 weeks after intervention</td>
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<tr>
<td><strong>Method of measurement</strong></td>
<td>with chronometer</td>
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### Secondary outcomes

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<tr>
<td><strong>Description</strong></td>
<td>Drug adverse effect</td>
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<tr>
<td><strong>Timepoint</strong></td>
<td>Before intervention, 4 weeks after intervention, 8 weeks after intervention</td>
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<tr>
<td><strong>Method of measurement</strong></td>
<td>Interview with patient</td>
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## Intervention groups

### 1

**Description**
Citalopram, 20mg, orally, every 12 hours for 8 weeks

**Category**
Treatment - Drugs

### 2

**Description**
Citalopram, 20mg, orally, 4 hours before coitus for 8 weeks

**Category**
Treatment - Drugs

## Recruitment centers

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<tr>
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<td><strong>Name of recruitment center</strong></td>
<td>Private clinic</td>
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<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>
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## Sponsors / Funding sources

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<tr>
<td><strong>Sponsor</strong></td>
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<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>
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<td><strong>Grant name</strong></td>
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<td><strong>Title of funding source</strong></td>
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<td><strong>Proportion provided by this source</strong></td>
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<tr>
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Person responsible for general inquiries

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Person responsible for updating data

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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