# Atosiban as a potential treatment for endometriosis

Published: 30-04-2019
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To investigate the potential of atosiban as a treatment for pain caused by endometriosis.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Menstrual cycle and uterine bleeding disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON47936

**Source**
ToetsingOnline

**Brief title**
ENDOBAN pilot-study

### Condition

- Menstrual cycle and uterine bleeding disorders

**Synonym**
Endometrium outside of the uterus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** Atosiban, Dysmenorroe, Endometriosis

## Outcome measures

### Primary outcome

Reduction in pain score on a visual analog scale

### Secondary outcome

Use of analgisics, experienced and observed side effects, oxytocin and

prostaglandin serum levels before and after admission.

# Study description

### Background summary

Endometriosis is a common chronic, incurable condition of unknown etiology in which endometrium-like tissue implants outside the uterus. In the Netherlands 405,000 women are estimated to have endometriosis in some degree. Symptoms may vary through the menstrual cycle and include but are not limited to: dysmenorrhea, chronic pelvic pain, dyspareunia and dyschezia. Current treatment consists of analgesics, hormonal treatment and more or less invasive surgery. Following histological findings and in vitro and animal research oxytocin receptor antagonist might be an alternative, non-hormonal, non-invasive treatment option. Except for one study on advanced reproductive techniques, no studies have reported the use of oxytocin receptor antagonists in human patients. We hypothesize atosiban can significantly lower patient*s pain scores. If this pilot study shows atosiban can be a treatment option for women with endometriosis, we intend to develop a patient-friendly mode of administration for atosiban.

### Study objective

To investigate the potential of atosiban as a treatment for pain caused by endometriosis.

### Study design

Phase II interventional pilot study

### Intervention

Atosiban 6,75 mg intravenously bolus, followed by 18 mg per hour continuous

infusion for 3 hours, followed by 6 mg per hour continuous infusion for 3 more hours.

### Study burden and risks

Participants will be admitted in day-care while they will receive intravenous treatment with atosiban. They will be asked to keep a menstrual diary for one month, one time before the treatment and another time afterwards. Besides participants will be asked to fill in questionnaires on quality of life and their medical history. Their pain-scores will be taken at several time points. We will take blood samples at the start and at the end of the treatment. The most important risk for participants is the risk on side effects related to atosiban. Side effect include nausea (>10%) headache, dizziness, flushes, tachycardia, hypotension, vomiting, hypoglycaemia and local reaction on the place of injection (1-10%). The most severe side effect described is pulmonary oedema. This was mostly in combination with other tocolytic agents and very rare, the side effects are generally considered to be mild. Atosiban has been administered on a routine basis to pregnant women in the same regimen as we will use now. However we will administer atosiban for a shorter period of time. According to the risk classification of the NFU (The Netherlands Federation of University Medical Centres) for patients participating in this study, the risk has been assessed as "moderate".

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- Laparoscopic, MRI or ultrasound confirmed endometriosis
- Dysmenorrhea with painscore >=5 during menstrual period or withdrawal bleeding
- Age between 18 and 45 years old

### Exclusion criteria

- Inability to come to the hospital for the experiment
- Suspicion on a (post)menopausal state
- Continuous treatment with oral contraceptives or progestagens
- Current use of GnRh antagonist
- Current ovarian stimulation
- Current breastfeeding
- Labour or breastfeeding within the last 6 weeks
- Diagnosis of chronic pelvic pain
- Inability to give informed consent
- Language barrier
- Diabetes Mellitus, type I or II
- Hypersensitivity to atosiban or mannitol
- Use of systemic betamimetics
- Use of calcium channel blockers

## Study design

### Design

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| Study phase: | 2 |
| Study type: | Interventional |

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-03-2022 |
| Enrollment: | 32 |
| Type: | Actual |

### Medical products/devices used

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| Product type: | Medicine |
| Brand name: | Tractocile |
| Generic name: | Atosiban |
| Registration: | Yes - NL outside intended use |

## Ethics review

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| Approved WMO Date: | 30-04-2019 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 04-02-2020 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2018-003324-3-NL |
| CCMO | NL67501.091.18 |