# A RANDOMIZED, TWO-PERIOD, OPEN-LABEL, SINGLE DOSE CROSSOVER STUDY TO EVALUATE THE BIOEQUIVALENCE OF AQX-1125 IMMEDIATE RELEASE TABLETS AND CAPSULES IN HEALTHY VOLUNTEERS

Published: 22-09-2015
Last updated: 19-04-2024

The purpose of the study is to investigate how quickly and to what extent AQX 1125 in the tablet form and the capsule form are absorbed and eliminated from the body (this is called pharmacokinetics). The pharmacokinetics of AXQ 1125 after...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bladder and bladder neck disorders (excl calculi) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON42576

**Source**
ToetsingOnline

**Brief title**
AQX-1125 Bioequivalence Study

### Condition

- Bladder and bladder neck disorders (excl calculi)

**Synonym**
Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS)

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Aquinox Pharmaceuticals (Canada) Inc.
**Source(s) of monetary or material Support:** farmaceutische industrie

## Intervention

**Keyword:** AQX-1125, Bioequivalence

## Outcome measures

### Primary outcome

Safety:

Adverse events, clinical laboratory, vital signs, 12-lead electrocardiogram and

physical examination

Pharmacokinetics:

Plasma AQX 1125 (and related product) concentrations

Plasma PK parameters estimated using noncompartmental analysis, as appropriate:

Cmax, tmax, kel, t1/2, AUC0-inf, %AUCextra, AUC0-t, CL/F and Vz/F

### Secondary outcome

NA

# Study description

### Background summary

AQX 1125 is a new investigational compound that is currently being investigated for the treatment of inflammatory diseases such as Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS). AQX 1125 activates the protein called SHIP1. The SHIP1 protein is involved in diverse processes in your body including cell growth, cell activation and the regulation of your immune system.

## Study objective

The purpose of the study is to investigate how quickly and to what extent AQX 1125 in the tablet form and the capsule form are absorbed and eliminated from the body (this is called pharmacokinetics). The pharmacokinetics of AXQ 1125 after administration as an oral capsule (which has already been investigated) will be compared to administration of AXQ 1125 as 2 new oral tablets. The tolerability (any side effects) of AQX-1125 will also be investigated.

## Study design

The actual study will consist of 2 periods during which you will stay in the clinical research center in Zuidlaren for 7 days (6 nights). The washout period between dosing in Period 1 and dosing in Period 2 will be 14 days. This washout period is to ensure that the study compound is no longer present in your body at the time you receive the second dose of AQX 1125.

The volunteer will receive AQX 1125 after an overnight fast (at least 10 hours no eating and drinking) either as an oral capsule (Treatment A) or 2 oral tablets (Treatment B) with 240 milliliters of tap water.

For both treatments it is applicable that fasting will continue until 4 hours after administration of the study compound. Then the volunteer will receive a lunch. During fasting it is allowed to drink water with the exception of 2 hours prior to until 1 hour after administration of the study compound.

## Intervention

The study will consist of 2 periods. In one period the volunteer will receive a single dose of 200 mg AQX 1125 in the form of an oral capsule (Treatment A), in the other period the volunteer will receive a single dose of 200 mg AQX 1125 in the form of 2 oral tablets (100 mg each) (Treatment B).

The order in which the volunteer will receive these treatments (Treatment A-B or Treatment B-A) will be determined by chance.

## Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

To date, 5 completed clinical studies have been performed with the AQX 1125 oral capsule formulation. Approximately 340 healthy volunteers and patients have received AQX 1125. Two completed studies tested the 200 mg AQX-1125 capsule in patients with either IC/BPS or chronic obstructive pulmonary disease. A total of 237 patients received once daily doses of 200 mg AQX 1125 for 6 weeks and 200 patients received once daily doses for 12 weeks. Single and

multiple doses (once daily for up to 10 days) of AQX 1125 up to doses of 542 mg in volunteers were also well tolerated. The most frequently observed adverse effects were diarrhea, nausea, dyspepsia (belly discomfort), abdominal (belly) pain and headache.

# Contacts

**Public**
Aquinox Pharmaceuticals (Canada) Inc.

887 Great Northern Way Suite 450
Vancouver BC V5T 4T5
CA
**Scientific**
Aquinox Pharmaceuticals (Canada) Inc.

887 Great Northern Way Suite 450
Vancouver BC V5T 4T5
CA

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Gender: Males and/or females
Age: 18 - 55 years, inclusive
BMI: 18.5 * 30.0 kg/m2, inclusive
Status: Healthy subjects

### Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-10-2015 |
| Enrollment: | 18 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 22-09-2015 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 25-09-2015 |
| Application type: | First submission |

| | |
|---|---|
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# 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 | EUCTR2015-003758-42-NL |
| CCMO | NL54911.056.15 |