# A phase 1 study to evaluate the absorption, metabolism and excretion of BCX7353 following administration of a single, oral dose of [14C]-radiolabeled BCX7353 to healthy male subjects.

Published: 14-08-2017
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The purpose of this study is to investigate how quickly and to what extent BCX7353 is absorbed, metabolized (changed or broken down by the body) and eliminated from the body (this is called pharmacokinetics). For this study BCX7353 will be labelled...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44289

**Source**
ToetsingOnline

**Brief title**
BCX7353 ADME Study

### Condition

- Other condition

**Synonym**
extremities, gastrointestinal tract and upper airways., genitals, Swelling of face

**Health condition**

Generische aandoening.

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** BioCryst Pharmaceuticals, Inc.
**Source(s) of monetary or material Support:** Farmaceutische Industrie.

## Intervention

**Keyword:** BCX7353, Hereditary angioedema

## Outcome measures

### Primary outcome

To determine the mass balance of [14C]-BCX7353.

### Secondary outcome

To determine the radioprofile and identify metabolites of [14C]-BCX7353 in

plasma, urine and feces following a single oral dose of [14C]-BCX7353

To assess the pharmacokinetics (PK) of BCX7353 in plasma and urine following

administration of an oral dose of [14C]-BCX7353

To assess the PK of total radioactivity in plasma

To assess the exposure of notable radiolabeled components using *AUC pooling*

To provide additional safety and tolerability information for BCX7353

# Study description

### Background summary

BCX7353 is a new compound that may eventually be used for the treatment of hereditary angioedema. Hereditary angioedema is a rare genetic disorder that causes episodes of swelling that may affect the face, extremities, genitals, gastrointestinal tract and upper airways. BCX7353 blocks a step in a series of reactions leading to the activation of bradykinin, a small enzyme (a peptide) involved in controlling the blood pressure by widening the blood vessels.

Bradykinin is thought to play an important role in the episodes of swelling.

**Study objective**

The purpose of this study is to investigate how quickly and to what extent BCX7353 is absorbed, metabolized (changed or broken down by the body) and eliminated from the body (this is called pharmacokinetics). For this study BCX7353 will be labelled with 14 Carbon (14C) and is thus radioactive. In this way BCX7353 can be traced in blood, urine, feces, and exhaled air.

It will also be investigated how safe the new compound BCX7353 is when it is administered to healthy subjects.

BCX7353 has been administered to healthy volunteers and patients suffering from hereditary angioedema in 7 studies. Of these studies 2 were completed and the results are known, 2 have been completed but no results are known yet and 3 are still ongoing.

**Study design**

BCX7353 is a new compound that may eventually be used for the treatment of hereditary angioedema. Hereditary angioedema is a rare genetic disorder that causes episodes of swelling that may affect the face, extremities, genitals, gastrointestinal tract and upper airways. BCX7353 blocks a step in a series of reactions leading to the activation of bradykinin, a small enzyme (a peptide) involved in controlling the blood pressure by widening the blood vessels. Bradykinin is thought to play an important role in the episodes of swelling.

The actual study will consist of 1 period during which the volunteers will stay in the research center in Groningen Martini Hospital for 16 to 22 days (15 to 21 nights). This may be followed by 1 to 4 24-hour visits to the research center.

Day 1 is the day of administration of the study compound. They are expected at the research center in the afternoon prior to the day of administration of the study compound. They will leave the research center between Day 15 and 21 of the study, depending on the amount of radioactivity excreted in the urine and feces. Twenty-four hour visits, which may also be required depending on the amount of radioactivity excreted, are planned on Days 28-29, 35 36, 42-43 and Day 49-50.

The participation in the entire study, from the pre-study screening until the last visit, will depend on the amount of radioactivity left in the urine and feces at the end of the study (Day 21). The amount of radioactivity in urine and feces will be measured daily from Day 1. If, from Day 15 onwards, the radioactivity levels in urine and feces are below the pre-defined levels, the

volunteers will be allowed to leave the research center upon completion of the discharge assessments.

If the amount of radioactivity in the urine and/or feces are not below the pre-defined levels on Day 21, they will return to the research center for 24-hour collection of urine and feces. For these collection intervals, they are expected in the research center at 10 AM of Day 28, 35, 42 and Day 49, and they can leave after the 24 hour collection interval (Day 29, 36, 43 and Day 50). After each 24-hour period you will be contacted to inform the volunteer whether they will be required to return for another 24-hour period.

### Intervention

Not applicable.

### Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

## Contacts

**Public**
BioCryst Pharmaceuticals, Inc.

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US
**Scientific**
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US

## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

healthy male subjects
18 - 65 years
BMI 18.0 - 32.0 kilograms/meter2
non smoking

## 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

**Study type:** Interventional

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-09-2017 |
| Enrollment: | 7 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 14-08-2017 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 05-09-2017 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 13-10-2017 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 19-10-2017 |
| Application type: | Amendment |
| 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 | EUCTR2017□002506□12-NL |
| CCMO | NL62768.056.17 |