# CryoCure 1: Prospective, Multicenter, Investigation of the Adagio Cryoablation System in Subjects with Atrial Flutter

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The objective of the study is to demonstrate the safety and feasibility of the Adagio Cryoablation System in subjects with Atrial Flutter (AFL).

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

## Summary

### ID

NL-OMON47270

**Source**
ToetsingOnline

**Brief title**
CryoCure 1

### Condition

- Cardiac arrhythmias

**Synonym**
abnormal heart rhythm, atrial flutter

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Biotechnologische Industrie
**Source(s) of monetary or material Support:** industry

## Intervention

**Keyword:** Atrial Flutter, cardiac, cryoablation

## Outcome measures

### Primary outcome

Safety: Percentage of subjects experiencing cardiovascular specific adverse

events (CSAE) within thirty 30 days of the ablation procedure.

### Secondary outcome

*Acute Success: Percentage of subjects with termination of AFL and complete

bidirectional conduction block across the subeustachian

(cavo-*tricuspid) isthmus at the end of the ablation procedure.

*Outcome success: Percent of subjects with absence of AFl at 180 days.

# Study description

### Background summary

The aim of this study is to evaluate the Adagio Cryoablation System when used in subjects diagnosed with an abnormal heart rhythm called Atrial Flutter.

The Adagio Cryoablation System is a device that treats Atrial Flutter by applying very cold temperatures to areas of the heart muscle using a small catheter. When the very cold temperatures are applied to certain areas of the heart it creates a *line* in the heart tissue that may stop the Atrial Flutter.

### Study objective

The objective of the study is to demonstrate the safety and feasibility of the Adagio Cryoablation System in subjects with Atrial Flutter (AFL).

### Study design

The study is a Prospective, Multicenter, Investigation of the Adagio

Cryoablation System in Subjects with Arterial Flutter

## Intervention

The Adagio Cryoablation System consist of the Cryoablation ablation catheter and a Cryoablation console. The Adagio Cryoablation System creates cryothermy energy by pressurizing nitrogen to critical pressures (CN2).

The Adagio Cryoablation Catheter includes closed, internal lumen where non-* insulated portions (freeze zone) achieve cryoablation temperatures. The freeze zone (distal tip / portion) is the only portion of the catheter where cyrothermy energy is distributed or exposed, a vacuum channel surrounds the closed, internal lumens insulating the non-*freezing portions from cold temperatures. The Cryoablation Catheter includes a thermocouple to measure temperature at its distal portion (freeze zone) for operational status.

The Cryoablation Catheter is delivered to the right upper chamber of the human heart via common femoral vein cannulation and delivers cold temperatures to specific heart features in order to ablate targeted tissue. The treatment is achieved by ablating (or isolating) the arrythmogenic tissue in contact with distal freeze zone of the catheter. During the treatment, the tissue in direct contact with the distal freeze zone drops to cryogenic temperatures resulting in necrosis (ablation) of the tissue.

The design of the Adagio Cryoablation Catheter freeze zone is able to create linear lesions, providing a greater assurance that the arrythmogenic tissue/regions are isolated, creating a bidirectional block, which will result in normal sinus rhythm.

## Study burden and risks

RISKS
The use of the investigational device will not expose you to significant additional risks above the risks of the regular medical care for Atrial Flutter ablation treatment. The investigational device does not require deviation from the hospital regular medical care for this type of procedure.

Use of an ablation catheter could cause prolonged illness, permanent impairment of daily function, or in rare cases, death. These risks are typically controlled through the use of medications, and a variety of other devices and procedures.

Adagio Medical representatives may be present at the procedure to provide technical support for both the Adagio Cryoablation System and the study protocol. There may be side effects that are not known at this time.

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you are fertile, you will be asked to take a pregnancy test before you will be allowed to participate in the study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

Other Risks
Patient's condition may not get better or may get worse during this study.

BENEFITS
Patient's Atrial Flutter may improve while they are in this study; however, this cannot be promised. The results of this study may help people with Atrial Flutter in the future.

## Contacts

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Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**

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

### Inclusion criteria

Two symptomatic episodes of typical AFl (or chronic atrial flutter) during the one-year period prior to enrollment. This may include typical AFl occurring while receiving AAD therapy for non-AFl tachyarrhythmia, including AFl.

### Exclusion criteria

Intra-cardiac thrombus has not been eliminated in subjects exposed to less than 4 weeks of therapeutic anticoagulation and a TEE (trans-esophageal echocardiogram) and/or CT scan did not conclusively rule out thrombus

## Study design

### Design

**Study type:** Interventional

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-02-2015 |
| Enrollment: | 25 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Adagio PolarStar System |
| Registration: | No |

## Ethics review

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| Approved WMO Date: | 26-11-2014 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 28-01-2015 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 30-11-2015 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 17-05-2016 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 26-01-2017 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 02-10-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 31-10-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 |
|---|---|
| CCMO | NL49917.100.14 |