ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 01/02/2012

ClinicalTrials.gov ID: NCT00915356

Study Identification

Unique Protocol ID:	D3191C00009
Brief Title:	Intravenous Cardioversion of Atrial Fibrillation (AF) With AZD1305
Official Title:	A Double-blind, Randomised, Placebo-controlled, Multicentre, Dose-escalating Study of AZD1305 Given Intravenously for Cardioversion of Atrial Fibrillation
Secondary IDs:	2009-009862-15 (EudraCT No)

Study Status

Record Verification:	January 2012
Overall Status:	Completed
Study Start:	May 2009
Primary Completion:	December 2009 [Actual]
Study Completion:	December 2009 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 77,261 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: S-20090042 Board Name: Den Videnskabsetiske Komité for Region Syddanmark Board Affiliation: Den Videnskabsetiske Komité for Region Syddanmark Phone: +45 76401621 Email: komite@regionsyddanmark.dk
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration Czech Republic: State Institute for Drug Control Denmark: Danish Medicines Agency Hungary: National Institute of Pharmacy Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Norway: Norwegian Medicines Agency Poland: Ministry of Health Slovakia: State Institute for Drug Control Sweden: Medical Products Agency

Study Description

Brief Summary:	This study is being carried out to see which dose of AZD1305 is safe and effective in cardioverting atrial fibrillation into normal heart rhythm.
Detailed Description:	

Conditions

Conditions:	Atrial Fibrillation
Keywords:	AZD1305 intravenous cardioversion of Atrial Fibrillation

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	228 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 AZD1305 iv infusion	Drug: AZD1305 Intravenous (iv) single infusion given intravenously until successful conversion of Atrial Fibrillation (AF) to Sinus Rhythm (SR) occur or for a maximum of 30 minutes
Placebo Comparator: 2 Placebo iv infusion	Drug: Placebo iv single infusion given intravenously until successful conversion of Atrial Fibrillation (AF) to Sinus Rhythm (SR) occur or for a maximum of 30 minutes

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	20 Years
Maximum Age:	80 Years
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Clinical indication for cardioversion of Atrial Fibrillation, ie a correction of irregular heart rhythm to normal heart rhythm
- Current episode of Atrial Fibrillation (ie irregular heart rhythm) lasting up to 3 months at randomisation
- Adequate anticoagulation according to international guidelines (ACC/AHA/ESC, 2006) or national guidelines

Exclusion Criteria:

- Potassium level below 3.8 mmol/L measured in serum or plasma
- QTcF interval >440 ms

Contacts/Locations

Study Officials: AZD1305 Medical Science Director
Study Director
AstraZeneca R&D Mölndal Sweden

Aladár Rónaszéki
Study Principal Investigator
Péterfy HospitalDepartment of Cardiology1076 Budapest, Péterfi Sándor str. 8-20HUNGARY

Locations: Czech Republic
Research Site
Brno, CZ, Czech Republic

Research Site
Praha 2, Czech Republic

Research Site
Znojmo, Czech Republic

Denmark
Research Site
Aalborg, Denmark

Research Site
Esbjerg, Denmark

Research Site
Svendborg, Denmark

Hungary
Research Site
Budapest, Hungary

Research Site
Cegled, Hungary

Research Site
Debrecen, Hungary

Research Site
Kecskemet, Hungary

Research Site
Szekesfehervar, Hungary

Netherlands
Research Site
Breda, Netherlands

Research Site
Deventer, Netherlands

Research Site
Leeuwarden, Netherlands

Research Site
Sneek, Netherlands

Norway
Research Site
Hamar, Norway

Research Site
Oslo, Norway

Research Site
RUD, Norway

Research Site
Tromso, Norway

Poland
Research Site
Bytom, Poland

Research Site
Lubin, Poland

Research Site
Plock, Poland

Research Site

Ruda Slaska, Poland

Research Site
Torun, Poland

Research Site
Warszawa, Poland

Slovakia
Research Site
Martin, Slovakia

Research Site
Nitra, Slovakia

Research Site
Ruzomberok, Slovakia

Sweden
Research Site
Linkoping, Sweden

Research Site
Orebro, Sweden

Research Site
Stockholm, Sweden

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Recruitment Details	The 1st patient was enrolled in the study on 25 May 2009, and the last patient completed the study on 4 December 2009. In total, 228 patients were enrolled (at 33 centres) and of the 171 patients randomised 170 patients completed the study. There was no discontinuation of the Investigational Product (IP) due to an Adverse Event (AE) in the study.
Pre-Assignment Details	An enrolment visit (Visit 1) was done within 14 days before scheduled randomisation. Patients who fulfilled criteria and signed the informed consent form, could then be randomised at visit 2. The patients were to have ongoing Atrial Fibrillation with a clinical indication for cardioversion of Atrial Fibrillation (AF).

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Overall Study

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Started	26	45	45	12	43
Completed	25	45	45	12	43
Not Completed	1	0	0	0	0
Withdrawal by Subject	1	0	0	0	0

Baseline Characteristics

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Baseline Measures

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo	Total
Number of Participants	26	45	45	12	43	171
Age, Continuous Age (years) [units: Years] Mean (Standard Deviation)	65 (9)	65 (7)	64 (10)	66 (7)	66 (9)	65 (8)
Gender, Male/Female [units: Participants]						
Female	9	17	14	4	18	62
Male	17	28	31	8	25	109

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Dose-response Relationship for QTcF Interval of AZD1305

Measure Description	QTcF-QT interval corrected for the RR interval (the time elapsing between two consecutive R waves in the electrocardiogram (ECG)) using the Fridericia formula.For each of 3 consecutive beats (5 consecutive beats if AF) a manual measurement, preferably in lead V2, of QTend intervals was done.The mean QT values of the 3 consecutive beats (5 consecutive beats if AF) were, together with RR intervals, date & time of the ECG, entered into the eCase Report Form (eCRF).The selected beats had to be marked with calipers and noted together with measured values and calculations on the print-out and signed
Time Frame	At any time post randomisation until end of Holter recording (18-24 hours post start of drug infusion).
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	25	45	45	12	42
Dose-response Relationship for QTcF Interval of AZD1305 [units: ms] Mean (95% Confidence Interval)	461 (449 to 474)	486 (476 to 495)	490 (480 to 499)	482 (464 to 500)	440 (430 to 450)

2. Primary Outcome Measure:

Measure Title	Conversion of Atrial Fibrillation (AF) and Maintenance of Sinus Rhytm (SR)
Measure Description	Conversion of AF to SR with maintenance of SR maintained for at least 1 minute
Time Frame	Within 90 minutes from start of infusion
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	26	45	45	12	43
Conversion of Atrial Fibrillation (AF) and Maintenance of Sinus Rhytm (SR) [units: Percentage of patients converted to SR] Number (95% Confidence Interval)	7.7 (0.9 to 25.1)	17.8 (8.0 to 32.1)	37.8 (23.8 to 53.5)	50.0 (21.1 to 78.9)	0.0 (0.0 to 8.2)

3. Secondary Outcome Measure:

Measure Title	Wide QRS Tachycardias

Measure Description	Number of patients with wide QRS tachycardias, determined as significant arrhythmias by an Adjudication Committee (AC). The AC analysed and classified the occurrence of significant arrhythmias (other than AF or AFl) and pauses based on the 12-lead Holter reports. All pauses (≥3 sec) and all wide QRS complex tachycardias (≥3 beats, QRS ≥120 ms, and ≥120 bpm).
Time Frame	From start of study drug infusion until discharge from hospital on study day 2.
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	26	45	45	12	43
Wide QRS Tachycardias [units: Participants]	4	15	16	2	7

4. Secondary Outcome Measure:

Measure Title	Heart Rhythm. Number of Participants With Early Relapse Into AF.
Measure Description	Early relapse into AF within 5 minutes from obtaining the defined criterion for conversion to SR (i.e.1 minute in SR). Patients never converted are not included in the analysis.

Time Frame	Within 5 minutes following investigational product (IP) induced conversion, or direct current (DC) cardioversion, of AF to SR
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	24	34	40	9	34
Heart Rhythm. Number of Participants With Early Relapse Into AF. [units: Participants]	1	1	2	0	1

5. Secondary Outcome Measure:

Measure Title	Heart Rhythm. Number of Patients Remaining in SR up to 24 h Following Start of Study Drug Infusion
Measure Description	
Time Frame	During 24 hours following start of study drug infusion
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	26	45	45	12	43
Heart Rhythm. Number of Patients Remaining in SR up to 24 h Following Start of Study Drug Infusion [units: Participants]	23	34	36	10	33

6. Secondary Outcome Measure:

Measure Title	Heart Rhythm. Number of Patients Remaining in SR up to 13 to 18 Days Following Study Drug Infusion.
Measure Description	Number of patients in SR at day 13-18
Time Frame	During 13 to 18 days following study drug infusion
Safety Issue?	Yes

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	25	45	45	12	43
Heart Rhythm. Number of Patients Remaining in SR up to 13 to 18 Days Following Study Drug Infusion. [units: Participants]	14	23	25	7	22

7. Secondary Outcome Measure:

Measure Title	Study the Relationship Between Systemic Exposure and Response, With Special Regards to Conversion of AF to SR and the Effect on the QTcF Interval.
Measure Description	
Time Frame	Since this study is no longer intended to be part of any marketing authorisation application, the analyses addressing this objective were not conducted.
Safety Issue?	No

Outcome Measure Data Not Reported

8. Secondary Outcome Measure:

Measure Title	Maximal Observed Plasma Concentration of AZD1305
Measure Description	Plasma concentration of AZD1305

Time Frame	Up to 24 hours following start of study drug infusion
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	24	41	43	11	0
Maximal Observed Plasma Concentration of AZD1305 [units: mol/L] Median (Full Range)	0.521 (0.157 to 0.991)	1.28 (0.374 to 2.97)	1.39 (0.017 to 3.17)	1.69 (0.873 to 3.61)	

9. Secondary Outcome Measure:

Measure Title	Conversion From AF to SR Within 90 Minutes From Start of Infusion in the Subgroup of Patients With Duration of Current AF Episode 10 Hours to 7 Days
Measure Description	
Time Frame	Conversion from AF to SR within 90 minutes from start of infusion
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	3	5	7	1	5
Conversion From AF to SR Within 90 Minutes From Start of Infusion in the Subgroup of Patients With Duration of Current AF Episode 10 Hours to 7 Days [units: Participants]	0	2	5	1	0

10. Secondary Outcome Measure:

Measure Title	Conversion From AF to SR Within 90 Minutes From Start of Infusion in the Subgroup of Patients With Duration of Current AF Episode 8 Days - 30 Days.
Measure Description	Subgroup analysis for patients with duration of current AF episode 8 days - 30 days. Number of patients converting from AF to SR.
Time Frame	Conversion from AF to SR within 90 minutes from start of infusion
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	5	13	16	4	8
Conversion From AF to SR Within 90 Minutes From Start of Infusion in the Subgroup of Patients With Duration of Current AF Episode 8 Days - 30 Days. [units: Participants]	0	4	6	2	0

11. Secondary Outcome Measure:

Measure Title	Conversion From AF to SR Within 90 Minutes From Start of Infusion in the Subgroup of Patients With Duration of Current AF Episode 31 Days - 3 Months
Measure Description	Subgroup analysis for patients with duration of current AF episode 31 days – 3 months. Number of patients converting from AF to SR.
Time Frame	Conversion from AF to SR within 90 minutes from start of infusion
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	18	27	22	7	30
Conversion From AF to SR Within 90 Minutes From Start of Infusion in the Subgroup of Patients With Duration of Current AF Episode 31 Days - 3 Months [units: Participants]	2	2	6	3	0

12. Secondary Outcome Measure:

Measure Title	Percentage of Patients, Discharged Within 6 h (QTcF ≤500 ms) After Start of Infusion
Measure Description	Percentage, with 95% confidence interval, of patients with QTcF≤500 ms six hours following start of study drug infusion
Time Frame	Six hours following start of study drug infusion
Safety Issue?	Yes

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Measured Values

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
Number of Participants Analyzed	23	44	45	12	40
Percentage of Patients, Discharged Within 6 h (QTcF ≤500 ms) After Start of Infusion [units: Percent of participants] Number (95% Confidence Interval)	100.0 (85.2 to 100.0)	95.5 (84.5 to 99.4)	91.1 (78.8 to 97.5)	100.0 (73.5 to 100.0)	100.0 (91.2 to 100.0)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
AZD1305 Dose Group 1	AZD1305, intravenous (IV) single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 50 mg/h.
AZD1305 Dose Group 2	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 101 mg/h.

	Description
AZD1305 Dose Group 3	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 130 mg/h.
AZD1305 Dose Group 4	AZD1305, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h, dose rate 180 mg/h.
Placebo	Sodium chloride, iv single infusion given intravenously until successful conversion of Atrial Fibrillation to Sinus Rhythm occur or for a maximum of 30 minutes. Infusion rate 120 ml/h.

Serious Adverse Events

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/	3/	3/	1/	2/
Cardiac disorders					
Atrial fibrillation [A] †	1/26 (3.85%)	1/45 (2.22%)	0/45 (0%)	0/12 (0%)	0/43 (0%)
Cardiac asthma [A] †	0/26 (0%)	0/45 (0%)	1/45 (2.22%)	0/12 (0%)	0/43 (0%)
Sinus bradycardia [A] †	1/26 (3.85%)	0/45 (0%)	0/45 (0%)	0/12 (0%)	0/43 (0%)
Torsade de pointes [A] †	0/26 (0%)	0/45 (0%)	1/45 (2.22%)	0/12 (0%)	0/43 (0%)
Ventricular tachycardia [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)
Gastrointestinal disorders					
Abdominal wall haematoma [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	0/12 (0%)	1/43 (2.33%)
Infections and infestations					
Urinary tract infection [A] †	0/26 (0%)	0/45 (0%)	1/45 (2.22%)	0/12 (0%)	0/43 (0%)
Injury, poisoning and procedural complications					
Multiple drug overdose [A] †	0/26 (0%)	1/45 (2.22%)	0/45 (0%)	0/12 (0%)	0/43 (0%)
Nervous system disorders					
Cerebrovascular accident [A] †	0/26 (0%)	1/45 (2.22%)	0/45 (0%)	0/12 (0%)	0/43 (0%)
Presyncope [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Transient ischaemic attack [A] †	0/26 (0%)	0/45 (0%)	1/45 (2.22%)	0/12 (0%)	0/43 (0%)
Respiratory, thoracic and mediastinal disorders					
Chronic obstructive pulmonary disease [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	0/12 (0%)	1/43 (2.33%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	5/26 (19.23%)	9/45 (20%)	8/45 (17.78%)	3/12 (25%)	5/43 (11.63%)
Cardiac disorders					
Angina pectoris [A] †	2/26 (7.69%)	0/45 (0%)	0/45 (0%)	0/12 (0%)	0/43 (0%)
Atrial fibrillation [A] †	3/26 (11.54%)	6/45 (13.33%)	5/45 (11.11%)	0/12 (0%)	4/43 (9.3%)
Bradycardia [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)
Ventricular tachycardia [A] †	1/26 (3.85%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)
Infections and infestations					
Gastritis fungal [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)
Musculoskeletal and connective tissue disorders					
Sensation of heaviness [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)
Nervous system disorders					
Dizziness [A] †	1/26 (3.85%)	0/45 (0%)	1/45 (2.22%)	1/12 (8.33%)	1/43 (2.33%)
Presyncope [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)
Tension headache [A] †	0/26 (0%)	0/45 (0%)	0/45 (0%)	1/12 (8.33%)	0/43 (0%)

	AZD1305 Dose Group 1	AZD1305 Dose Group 2	AZD1305 Dose Group 3	AZD1305 Dose Group 4	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Vascular disorders					
Hypertension [A] †	0/26 (0%)	3/45 (6.67%)	2/45 (4.44%)	0/12 (0%)	0/43 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

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