Clinical trial results:
Effect of Strict Control of Blood Sugar with Insulin Regimen on Prevention of Atrial Fibrillation after Coronary Artery Bypass Grafting.

Summary

EudraCT number	2004-004348-39
Trial protocol	GB
Global end of trial date	04 July 2008

Results information

Result version number	v1 (current)
This version publication date	19 February 2021
First version publication date	19 February 2021
Summary attachment (see zip file)	End of study report (2007-007877-22_Declarationof End of Trial Notification Form_29Dec2011.pdf)

Trial information

Trial identification

Sponsor protocol code	2004HS0191H

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Royal Brompton and Harefield NHS Foundation Trust
Sponsor organisation address	Research Office, Sydney Street, London, United Kingdom, SW3 6NP
Public contact	Ira Jakupovic, Royal Brompton and Harefield NHS Foundation Trust, 3518109 3518109, i.jakupovic@rbht.nhs.uk
Scientific contact	Ira Jakupovic, Royal Brompton and Harefield NHS Foundation Trust, 3518109 3518109, i.jakupovic@rbht.nhs.uk
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 July 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 May 2008
Global end of trial reached?	Yes
Global end of trial date	04 July 2008
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Prevention of Atrial Fibrillation following Coronary Artery Bypass Grafting.

Protection of trial subjects:

n/a

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 September 2005
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 77
Worldwide total number of subjects	77
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	77
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients admitted for primary, isolated CABG, were recruited to participate in the study. A total 88 patients were enrolled for the study between September 2005 and May 2008.

Pre-assignment

Screening details:

n/a

Period 1

Period 1 title	Overal Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

n/a

Arms

Are arms mutually exclusive?	Yes
Arm title	Soluble Insuling Actrapid

Arm description:

Control Group – The patients were treated routinely with intravenous insulin when blood glucose level exceeds 10 mmol/L.

Arm type	Active comparator
Investigational medicinal product name	Soluble Insulin Actrapid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Control Group – The patients were treated routinely with intravenous insulin when blood glucose level exceeds 10 mmol/L.

Arm title	Soluble Insulin Actrapid with Algorithm

Arm description:

Treatment Group - Patients were treated with intravenous insulin using the Algorithm for Intensive Insulin Therapy to maintain blood glucose between 4.0 to 6.0 mmol/L starting from the time of induction for surgery and continued for 96 hours post-operatively.

Arm type	Experimental
Investigational medicinal product name	Actrapid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Treatment Group - Patients were treated with intravenous insulin using the Algorithm for Intensive Insulin Therapy to maintain blood glucose between 4.0 to 6.0 mmol/L starting from the time of induction for surgery and continued for 96 hours post-operatively.

Number of subjects in period 1	Soluble Insuling Actrapid	Soluble Insulin Actrapid with Algorithm
Started	41	36
Completed	41	36

Baseline characteristics

End points

End points reporting groups

Reporting group title	Soluble Insuling Actrapid

Reporting group description:

Control Group – The patients were treated routinely with intravenous insulin when blood glucose level exceeds 10 mmol/L.

Reporting group title	Soluble Insulin Actrapid with Algorithm

Reporting group description:

Treatment Group - Patients were treated with intravenous insulin using the Algorithm for Intensive Insulin Therapy to maintain blood glucose between 4.0 to 6.0 mmol/L starting from the time of induction for surgery and continued for 96 hours post-operatively.

Primary: Incidence of AF

End point title	Incidence of AF[1]

End point description:

The present study was undertaken to find out the incidence of atrial fibrillation on strict control of blood glucose with Insulin infusion up to four days following CABG. In addition, this study aimed to look after other beneficial effects of tight glycaemic control on the outcome after CABG. In this randomised trial, patients treated with insulin infusion to maintain blood glucose level between 4.0 to 6.0 mmol/L for four days were compared with control group receiving standard treatment after CABG.

End point type	Primary

End point timeframe:

The incidence of atrial fibrillation on strict control of blood glucose with Insulin infusion up to four days following CABG.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Details of statistical analyis sumbitted with the end of study report.

End point values	Soluble Insuling Actrapid	Soluble Insulin Actrapid with Algorithm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	36		
Units: mmol/L	41	36		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the clinical trial were to be collected.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Attached is the final report study report, sent to the MHRA in 2008.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported