Clinical trial results:
Anglo-Scandinavian Cardiac Outcomes Trial; Post Trial Follow-Up Study

Summary

EudraCT number	2010-023875-24
Trial protocol	GB
Global end of trial date	30 May 2015

Results information

Result version number	v1 (current)
This version publication date	08 November 2019
First version publication date	08 November 2019

Trial information

Trial identification

Sponsor protocol code	CRO1777

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01499511
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Judith A Mackay, Imperial College London, +44 2075941395, judith.mackay@imperial.nhs.uk
Scientific contact	Judith A Mackay, Imperial College London, +44 2075941395, judith.mackay@imperial.nhs.uk

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	31 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 May 2015
Global end of trial reached?	Yes
Global end of trial date	30 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The principal research objective is to see whether there are long-term differences between the study treatments used in the original ASCOT study (atenolol-based vs perindopril-based treatment on blood pressure lowering, and atorvastatin versus placebo treatment on cholesterol lowering) in terms of cardiovascular disease (heart attacks, strokes and death from cardiovascular disease). Followup study without treatment

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 January 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	16 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 1718
Worldwide total number of subjects	1718
EEA total number of subjects	1718

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)	173
From 65 to 84 years	1417

85 years and over	128

Subject disposition

Recruitment

Recruitment details:

ASCOT-10 is a follow-up study of surviving participants in the United Kingdom (UK)arm of the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) which was conducted between 2000 and 2005.

Pre-assignment

Screening details:

It is follow up group from the ASCOT study, after 5.5 years treatment.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	ASCOT participants amlodipine

Arm description:

It is follow up group from the ASCOT study, after treatment with amlodipine for 5.5 years. No treatment only follow up.

Arm type	no intervention
Investigational medicinal product name	No product
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Other use

Dosage and administration details:

no intervention

Arm title	ASCOT Participants Atenolol

Arm description:

It is follow up group from the ASCOT study, after treatment with atenolol for 5.5 years. No treatment only follow up.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	ASCOT participants amlodipine	ASCOT Participants Atenolol
Started	885	833
Completed	884	833
Not completed	1	0
death	1	-

Baseline characteristics

Reporting groups	
Reporting group title	ASCOT participants amlodipine
Reporting group description:	
It is follow up group from the ASCOT study, after treatment with amlodipine for 5.5 years. No treatment only follow up.	
Reporting group title	ASCOT Participants Atenolol
Reporting group description:	
It is follow up group from the ASCOT study, after treatment with atenolol for 5.5 years. No treatment only follow up.	

Reporting group values	ASCOT participants amlodipine	ASCOT Participants Atenolol	Total
Number of subjects	885	833	1718
Age categorical Units: Subjects			
Adults (18-64 years)	85	88	173
From 65-84 years	731	686	1417
more than 85 years	69	59	128
Age continuous Units: years			
median	75	74.51	
full range (min-max)	53.97 to 92.54	52.36 to 91.03	-
Gender categorical Units: Subjects			
Female	739	720	1459
Male	146	113	259

End points

End points reporting groups

Reporting group title	ASCOT participants amlodipine
Reporting group description:	
It is follow up group from the ASCOT study, after treatment with amlodipine for 5.5 years. No treatment only follow up.	
Reporting group title	ASCOT Participants Atenolol
Reporting group description:	
It is follow up group from the ASCOT study, after treatment with atenolol for 5.5 years. No treatment only follow up.	

Primary: Morbidity after 16 years in patients recruited into the Anglo-Scandinavian Outcomes trial_non fatal myocardial infarction

End point title	Morbidity after 16 years in patients recruited into the Anglo-Scandinavian Outcomes trial_non fatal myocardial infarction
End point description:	
End point type	Primary
End point timeframe:	
16 years	

End point values	ASCOT participants amlodipine	ASCOT Participants Atenolol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	877	828		
Units: Participants	35	37		

Statistical analyses

Statistical analysis title	non fatal myocardial infarction
Comparison groups	ASCOT participants amlodipine v ASCOT Participants Atenolol
Number of subjects included in analysis	1705
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.624
Method	ANOVA
Parameter estimate	Cox proportional hazard

Primary: Morbidity After 16 Years in Patients Recruited Into the Anglo-Scandinavian Outcomes trial_non Fatal Stroke/TIA (Transient Ischaemic Attack)

End point title	Morbidity After 16 Years in Patients Recruited Into the Anglo-Scandinavian Outcomes trial_non Fatal Stroke/TIA (Transient Ischaemic Attack)

End point description:

End point type	Primary

End point timeframe:

16 years

End point values	ASCOT participants amlodipine	ASCOT Participants Atenolol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	877	823		
Units: Participants	29	52		

Statistical analyses

Statistical analysis title	non Fatal Stroke/TIA (Transient Ischaemic Attack)
Comparison groups	ASCOT participants amlodipine v ASCOT Participants Atenolol
Number of subjects included in analysis	1700
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	ANOVA

Secondary: Number of participants who have developed diabetes since the end of the ASCOT trial

End point title	Number of participants who have developed diabetes since the end of the ASCOT trial

End point description:

End point type	Secondary

End point timeframe:

16 years

End point values	ASCOT participants amlodipine	ASCOT Participants Atenolol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	871	825		
Units: Participants	322	325		

Statistical analyses

Statistical analysis title	Diabetes
Comparison groups	ASCOT participants amlodipine v ASCOT Participants Atenolol
Number of subjects included in analysis	1696
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.304
Method	ANOVA

Secondary: Number of Participants Who Have Undergone Coronary/Peripheral Re-vascularisation Procedures Since the End of the ASCOT Trial

End point title	Number of Participants Who Have Undergone Coronary/Peripheral Re-vascularisation Procedures Since the End of the ASCOT Trial

End point description:

End point type	Secondary

End point timeframe:

16 years

End point values	ASCOT participants amlodipine	ASCOT Participants Atenolol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	872	822		
Units: Participants	39	33		

Statistical analyses

Statistical analysis title	Coronary/Peripheral Re-vascularisation Procedures
Comparison groups	ASCOT participants amlodipine v ASCOT Participants Atenolol
Number of subjects included in analysis	1694
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.641
Method	ANOVA

Secondary: Number of Participants Who Have Required Renal Replacement Therapy (Dialysis or Kidney Transplant) Since the End of the ASCOT Trial

End point title	Number of Participants Who Have Required Renal Replacement Therapy (Dialysis or Kidney Transplant) Since the End of the ASCOT Trial

End point description:

End point type	Secondary

End point timeframe:

16 years

End point values	ASCOT participants amlodipine	ASCOT Participants Atenolol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	874	826		
Units: Participants	10	9		

Statistical analyses

Statistical analysis title	Required Renal Replacement Therapy
Comparison groups	ASCOT participants amlodipine v ASCOT Participants Atenolol
Number of subjects included in analysis	1700
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.915
Method	ANOVA

Adverse events

Adverse events information

Timeframe for reporting adverse events:

16 years follow up

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Reporting groups

Reporting group title	ASCOT participants amlodipine

Reporting group description:

It is follow up group from the ASCOT study, after treatment with amlodipine for 5.5 years. No treatment only follow up.

Reporting group title	ASCOT Participants Atenolol

Reporting group description:

It is follow up group from the ASCOT study, after treatment with atenolol for 5.5 years. No treatment only follow up.

Serious adverse events	ASCOT participants amlodipine	ASCOT Participants Atenolol	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 885 (0.23%)	0 / 833 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Stroke	Additional description: Ischaemic stroke		
subjects affected / exposed	1 / 885 (0.11%)	0 / 833 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Injuries	Additional description: Cycling accident		
subjects affected / exposed	1 / 885 (0.11%)	0 / 833 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	ASCOT participants amlodipine	ASCOT Participants Atenolol	
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 885 (0.45%)	1 / 833 (0.12%)	
Cardiac disorders High blood pressure subjects affected / exposed occurrences (all)	1 / 885 (0.11%) 1	0 / 833 (0.00%) 0	
Nervous system disorders Collapse subjects affected / exposed occurrences (all) Alcohol dependence withdrawal subjects affected / exposed occurrences (all)	0 / 885 (0.00%) 0 1 / 885 (0.11%) 1	1 / 833 (0.12%) 0 0 / 833 (0.00%) 0	
Gastrointestinal disorders Stomach cramp subjects affected / exposed occurrences (all)	1 / 885 (0.11%) 1	0 / 833 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Bronchiectasis subjects affected / exposed occurrences (all)	1 / 885 (0.11%) 1	0 / 833 (0.00%) 0	

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