Clinical trial results:
Effects of Zoledronic Acid on arterial calcification and arterial stiffness in women – a co-twin randomised double blind, placebo-controlled parallel group, clinical trial

Summary

EudraCT number	2010-019656-41
Trial protocol	GB
Global end of trial date	21 October 2014

Results information

Result version number	v1 (current)
This version publication date	17 October 2019
First version publication date	17 October 2019
Summary attachment (see zip file)	Cancelled Before Active Statement (Cancelled before Active Statement.pdf)

Trial information

Trial identification

Sponsor protocol code	ZA/CP/0210

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	King's College London
Sponsor organisation address	The Strand, London, United Kingdom, WC2R 2LS
Public contact	Professor P J Chowienczyk, King's College London, 0044 02071884642, phil.chowienczyk@kcl.ac.uk
Scientific contact	Professor P J Chowienczyk, King's College London, 0044 02071884642, phil.chowienczyk@kcl.ac.uk
Sponsor organisation name	Guy's & St Thomas' NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE19RT
Public contact	Dr P J Chowienczyk, Guy's and St Thomas' NHS Foundation Trust, 0044 02071884642, phil.chowienczyk@kcl.ac.uk
Scientific contact	Dr P J Chowienczyk, Guy's and St Thomas' NHS Foundation Trust, 0044 02071884642, phil.chowienczyk@kcl.ac.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	21 October 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Does Zoledronic Acid 5 mg once yearly compared to placebo reduces arterial stiffness?

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 October 2014
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

Pre-assignment

Screening details:

N.A

Period 1

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

Arms

Arm title	Z ACID

Arm description:

Zoledronic acid 5 mg solution for infusion

Arm type	Experimental
Investigational medicinal product name	Zoledronic Acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Dosage would have been Zoledronic Acid 5 mg solution for infusion

Number of subjects in period 1	Z ACID
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Z ACID

Reporting group description:

Zoledronic acid 5 mg solution for infusion

Primary: Number of subjects with Adverse Events (AEs): Part 1 [1]

End point title	Number of subjects with Adverse Events (AEs): Part 1 [1][1]

End point description:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

End point type	Primary

End point timeframe:

N/A

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: No subjects were enrolled in the trial hence results are not available

End point values	Z ACID			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: 1				
number (not applicable)	99999			

Notes:

[2] - [1] - No statistical analyses have been specified for this primary end point. It is expected there i

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.

Adverse event reporting additional description:

N/A

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	Z ACID

Reporting group description:

Zoledronic acid 5 mg solution for infusion

Serious adverse events	Z ACID		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Z ACID		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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: No subjects were enrolled in the trial hence results are not available

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in the trial hence results are not available

Notes: