Clinical trial results:
Antiplatelet and vascular effects of aspirin in healthy persons and patients with type 2 diabetes.

Summary

EudraCT number	2016-000515-32
Trial protocol	DK
Global end of trial date	02 December 2016

Results information

Result version number	v1 (current)
This version publication date	09 February 2018
First version publication date	09 February 2018

Trial information

Trial identification

Sponsor protocol code	2016-623

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Per Løgstrup Poulsen
Sponsor organisation address	Nørrebrogade 44, Aarhus, Denmark, 8000
Public contact	Coordinator, Liv Vernstrøm Hald, lvh@clin.au.dk
Scientific contact	Coordinator, Liv Vernstrøm Hald, lvh@clin.au.dk

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	01 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 December 2016
Global end of trial reached?	Yes
Global end of trial date	02 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim is to investigate the effect of aspirin on platelet aggregation, endothelial-dependent vasodilation and arterial stiffness during 24 hours in patients with type 2 diabetes without known cardiovascular disease and in healthy controls.

Protection of trial subjects:

Considering the small doses and short-term treatment, we found the risk minimal and acceptable. No specific measures were put in place.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 May 2016
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	Denmark: 43
Worldwide total number of subjects	43
EEA total number of subjects	43

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)	26
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Controls were recruited from an excisting study population and patients were recruited from the outpatient clinic at the department of endocrinology, Aarhus University Hospital.

Pre-assignment

Screening details:

Patients were screened according to in- and exclusion criteria. There were no screening-log.

Period 1

Period 1 title	Intervention (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Type 2 Diabetes

Arm description:

Patients with type 2 diabetes

Arm type	Experimental
Investigational medicinal product name	Aspirin
Investigational medicinal product code	
Other name	Acetylsalicylic-acid
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

75 mg, once daily

Arm title	Control group

Arm description:

Non-diabetic controls

Arm type	Experimental
Investigational medicinal product name	Aspirin
Investigational medicinal product code	
Other name	Acetylsalicylic-acid
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

75 mg, once daily

Number of subjects in period 1	Type 2 Diabetes	Control group
Started	22	21
Completed	21	21
Not completed	1	0
Consent withdrawn by subject	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Type 2 Diabetes
Reporting group description:	
Patients with type 2 diabetes	
Reporting group title	Control group
Reporting group description:	
Non-diabetic controls	

Reporting group values	Type 2 Diabetes	Control group	Total
Number of subjects	22	21	43
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			
median	61	62	
standard deviation	± 9	± 9	-
Gender categorical			
Units: Subjects			
Female	7	7	14
Male	15	14	29

End points

End points reporting groups	
Reporting group title	Type 2 Diabetes
Reporting group description: Patients with type 2 diabetes	
Reporting group title	Control group
Reporting group description: Non-diabetic controls	

Primary: 24-hour antiplatelet effect of aspirin	
End point title	24-hour antiplatelet effect of aspirin
End point description: Difference between aggregation level 1 hour and 24 hours after aspirin ingestion.	
End point type	Primary
End point timeframe: 24 hours	

End point values	Type 2 Diabetes	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: Aggregation units (AUC)				
arithmetic mean (standard deviation)	85 (± 101)	80 (± 105)		

Statistical analyses

Statistical analysis title	Mixed model analysis
Comparison groups	Type 2 Diabetes v Control group
Number of subjects included in analysis	42
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.05
Method	Mixed models analysis

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: First patients first visit to last patients last visit	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10

Reporting groups	
Reporting group title	Type 2 Diabetes
Reporting group description: Patients with type 2 diabetes	
Reporting group title	Control group
Reporting group description: Non-diabetic controls	

Serious adverse events	Type 2 Diabetes	Control group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Type 2 Diabetes	Control group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (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: There were no adverse events

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/29175435