Clinical trial results:
Effect of a preinterventional calorie restriction on renal function after contrast agent exposition in patients at risk.

Summary

EudraCT number	2012-003696-18
Trial protocol	DE
Global end of trial date	07 October 2016

Results information

Result version number	v1 (current)
This version publication date	26 December 2020
First version publication date	26 December 2020
Summary attachment (see zip file)	Final_Report_2020-03-12 (CR_KMN_Abschlussbericht_Synopse_V2_2020-03-12.pdf)

Trial information

Trial identification

Sponsor protocol code	uni-koeln-1547

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01879839
WHO universal trial number (UTN)	-
Other trial identifiers	DRKS: 00004361

Notes:

Sponsors

Sponsor organisation name	University of Cologne
Sponsor organisation address	Albertus-Magnus-Platz, Cologne, Germany, 50923
Public contact	Clinic II Internal Medicine PD. Dr. V Burst, University Hospital of Cologne, 0049 22147897222, volker.burst@uk-koeln.de
Scientific contact	Clinic II Internal Medicine PD. Dr. V Burst, University Hospital of Cologne, 0049 22147897222, volker.burst@uk-koeln.de

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	07 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 October 2016
Global end of trial reached?	Yes
Global end of trial date	07 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The intention of this trial is to investigate, if a short-term calorie restriction before contrast agent administration can prevent contrast induced nephropathy.

Protection of trial subjects:

Increase of creatinine in serum [mg/dl] 48 h after coronary intervention compared with creatinine in serum on day 0 before intervention

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 July 2013
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	Germany: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	5
From 65 to 84 years	73
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

First patient in: 10.07.2013
Last patient out: 07.10.2016

Pre-assignment

Screening details:

Inclusion: Patients with planned coronary intervetion and following diagnosis: pAVK, Creatinine >1,1 (m)/>0,9 (w), diabetes, hart failure with NYHA 3-4, signed consent
Exclusion: end stage kidney failure, kidney transplantation, underweight or obese, infection, allergy on ingredients of formula-diet, paricipation on another clinical trials

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Diet arm

Arm description:

Patients will receive special nutrition 4 days before the coronary intervention (day -4 till breakfast of day -1), afterwards fasting till coronary intervention on day 0.

Arm type	Experimental
Investigational medicinal product name	Fresubin® energy fibre Drink (Fresenius Kabi Deutschland GmbH, Bad Homburg, Deutschland).
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Patients get Fresubin® energy fibre Drink for three days vor intervetion and morning of day -1 (from day -4 till morning of day -1)

Investigational medicinal product name	Accupaque™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Dosage and administration according standard care of department III of University Hospital of Cologne

Arm title	Control Arm

Arm description:

Patients will allowed to eat ad libitum, they have any changes in their eating habits

Arm type	comparator
Investigational medicinal product name	Accupaque™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Dosage and administration according standard care of department III of University Hospital of Cologne

Number of subjects in period 1	Diet arm	Control Arm
Started	40	40
Completed	40	40

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	80	80	
Age categorical Units: Subjects			
Adults (18-64 years)	5	5	
From 65-84 years	73	73	
85 years and over	2	2	
Gender categorical Units: Subjects			
Female	20	20	
Male	60	60	

End points

End points reporting groups

Reporting group title	Diet arm
Reporting group description:	
Patients will receive special nutrition 4 days before the coronary intervention (day -4 till breakfast of day -1), afterwards fasting till coronary intervention on day 0.	
Reporting group title	Control Arm
Reporting group description:	
Patients will allowed to eat ad libitum, they have any changes in their eating habits	

Primary: Increase of creatinine in serum 48 h after coronary intervention (exposure of contrast agent)

End point title	Increase of creatinine in serum 48 h after coronary intervention (exposure of contrast agent)
End point description:	
End point type	Primary
End point timeframe:	
48 h after coronary intervention (exposure of contrast agent)	

End point values	Diet arm	Control Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	33		
Units: mg/dl				
arithmetic mean (standard deviation)	0.078 (± 0.35)	0.127 (± 0.21)		

Statistical analyses

Statistical analysis title	ANCOVA with Covariate Baseline-Creatinine
Statistical analysis description:	
The difference between serum creatinine 48h after the start of coronary intervention (contrast medium exposure) and serum creatinine on Day 0 before intervention is compared in the two trial groups by means of ANCOVA (baseline adjustment) in the ITT population. A PP analysis is also performed. Missing values were replaced with a last-observation-carried-forward approach.	
Comparison groups	Diet arm v Control Arm
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.49
Method	ANCOVA

Adverse events

Adverse events information

Timeframe for reporting adverse events:

10.07.2013-07.10.2016

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Reporting groups

Reporting group title	Diet Group
Reporting group description: -	
Reporting group title	Control Group

Reporting group description: -

Serious adverse events	Diet Group	Control Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Cardiac disorders			
Coronary artery disease	Additional description: Progression coronary artery disease		
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Ischemia	Additional description: Cardiac Ischemia		
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Diet Group	Control Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 40 (42.50%)	9 / 40 (22.50%)	
Injury, poisoning and procedural complications			

Groin hematoma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Lateral hematoma	Additional description: Lateral hematoma next to puncture site of cardiac catheter		
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Orthostatis dysregulation			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Hypotension			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	
occurrences (all)	1	2	
Tachyarrhytmia absoluta			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Thoracic pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Hematoma			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Unclear pain			

subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Thoracic pain rear sternum			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Numbness in right arm			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Numbness in right middel finger			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Numbness in right thigh			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Numbness in right leg			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Sensivity disorder in right leg			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 40 (7.50%)	2 / 40 (5.00%)	
occurrences (all)	3	2	
Hypokaliemia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	

Endocrine disorders Hyperglycemia subjects affected / exposed occurrences (all)	 1 / 40 (2.50%) 1	 0 / 40 (0.00%) 0	
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	 1 / 40 (2.50%) 1	 0 / 40 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 October 2015	Prolongation of study period because trial participations number was not reached in planned time.

Notes:

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.

There are any limitiations and caveats during study period

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/29535139