



## 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
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##### 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 intervention and following diagnosis: pAVK, Creatinine >1,1 (m)/>0,9 (w), diabetes, heart failure with NYHA 3-4, signed consent

Exclusion: end stage kidney failure, kidney transplantation, underweight or obese, infection, allergy on ingredients of formula-diet, participation 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
<b>Arm title</b>	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 intervention 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

<b>Arm title</b>	Control Arm
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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

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Dosage and administration details:

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

<b>Number of subjects in period 1</b>	Diet arm	Control Arm
Started	40	40
Completed	40	40

## Baseline characteristics

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### Reporting groups

Reporting group title	overall trial
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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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19
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### Reporting groups

Reporting group title	Diet Group
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Reporting group description: -

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

subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	1 / 40 (2.50%) 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:

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### 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 limitations and caveats during study period
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Notes:

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### Online references

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